

EPA Jacket 2517-173

Kumar, Rita

From: Kumar, Rita
Sent: Thursday, February 04, 2016 11:58 AM
To: Carrie Daniels
Cc: James Messina; Kelly Hoskins (Kelly.Hoskins@perrigo.com)
Subject: Pending application cat spot-on imidacloprid
Attachments: 2517-173-20160203.pdf

Please see attached. This action is now complete. Kindly acknowledge receipt.

Regards,
Rita



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

2517-173

Date of Issuance:

2/3/16

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
Expires: 2/3/18

Name of Pesticide Product:

Sergeant's 9.1% Imidacloprid Spot
On for Cats

Name and Address of Registrant (include ZIP Code):

Kelly R. Hoskins
Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-3710

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Venus Eagle, Product Manager 01
Invertebrate-Vertebrate Branch 3, Registration Division (7505P)

Date:

2/3/16

2. This registration is time-limited and expires 2/3/18.
3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. The following is a list of information that must be included in the quarterly reports for each incident:
 - EPA Registration Number
 - Product name (brand name)
 - Lot #
 - Where purchased: internet, store, veterinarian
 - Active Ingredient(s)
 - Weight range for product
 - Date on which incident occurred. (mm/dd/yyyy)
 - State in which the incident occurred. (standard 2 letter abbreviation)
 - Registrant case #
 - Species: dog, cat, other (specify)
 - Breed: (as reported by pet owner)
 - Age: months or years
 - Sex: M, F, or neutered
 - Weight: pounds
 - Primary Route of Exposure: dermal, oral, other animal, inhalation, other
 - Body System: neurological, dermatological, GI, respiratory, ocular, other
 - Major signs noted with separate column for each sign, using standard terminology
 - Time to Onset: (hours, days)
 - Treated by veterinarian: yes or no
 - First time product used: yes or no
 - Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
 - Any known precondition
 - EPA Severity Code: death, major, moderate, minor
 - Outcome: died, recovered, still treated, unknown
4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
 - All incidents should be reported including all minor dermal and ocular irritation reports.
 - Summary table for cats showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.

- A similar summary table for dogs (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for cats showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of cat incidents for each severity code for each pet weight range on the product label, as applicable.
- A summary table for cat weight showing number of incidents for each product weight range. This table should show number of incidents in cats weighing less than that product weight range, number of incidents in cats in lower half of weight range, number of incidents in cats in upper half of weight range, and cats weighing more than the product weight range, as applicable.
- Table showing number of incidents for each cat breed, where provided.
- Table showing number of incidents in cats for each clinical sign.
- Table showing number of incidents in cats for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

5. You are required to comply with the data requirements described in the DCI or EDSP Order identified below:
 - a. Imidacloprid GDCI-129099-951
 - b. Imidacloprid EDSP-129099

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI or EDSP Order listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:

http://www.epa.gov/oppsrrd1/contacts_prd.htm

6. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 2517-173."
7. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is

referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 12/30/2015

If you have any questions, please contact Rita Kumar by phone at (703) 308-8291, or via email at kumar.rita@epa.gov.

Enclosure: Stamped label

Sergeant's® Master Label

15 January 2016

Version 15.1

EPA Reg. No. 2517-RTG

Information in [] is optional.

Information in { } is note to reviewer.

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FRONT PANEL Cats Spot On

Imidacloprid

[Optional text appears in brackets/parenthesis – the final label may include some or all of the optional text on front, back or side label panels]

Sergeant's® 9.1% Imidacloprid Spot On for Cats

{Market Label-the word Cat will be at least 40-75% in height of the largest letter in the primary brand name.}

{Market Label-a large clear picture of a cat in the respective weight range will be on the front panel of the label.}

{One of the following statements will appear on appropriate weight band market label front panel as required per Agency's pet spot-on mitigation measures:}

For use ONLY on cats [[&][and] kittens] [weighing] 2 [-][to] 9 lbs. and over 8 weeks [old][of age] {0.4 ml size package}

For use ONLY on cats [[&][and] kittens] [weighing] 2 [-][to] 9 lbs. and 8 weeks [of age] or older {0.4 ml size package}

For use ONLY on cats [[&][and] kittens] [weighing] [more than][over][>] 9 lbs. and over 8 weeks [old][of age] {0.8 ml size package}

For use ONLY on cats [[&][and] kittens] [weighing] [more than][over][>] 9 lbs. and 8 weeks [of age] or older {0.8 ml size package}

ONLY for cats [[&][and] kittens] over 8 weeks [old][of age] and [weighing] 2 [-][to] 9 lbs. {0.4 ml size package}

ONLY for cats [[&][and] kittens] 8 weeks [of age] or older and [weighing] 2 [-][to] 9 lbs. {0.4 ml size package}

ONLY for cats [[&][and] kittens] over 8 weeks [old][of age] and [weighing] [more than][over][>] 9 lbs. {0.8 ml size package}

ONLY for cats [[&][and] kittens] 8 weeks [of age] or older and [weighing] [more than][over][>] 9 lbs. {0.8 ml size package}

ACTIVE INGREDIENT:

Imidacloprid.....9.10%

OTHER INGREDIENTS:90.90%

[TOTAL]100.00%

KEEP OUT OF REACH OF CHILDREN WARNING

See [Back][or][Side][Label[s]][Panel[s]] for Additional Precautionary Statements

NET CONTENT: X fl oz [Y – X fl oz applicators]

[0.014 fl oz (0.4 mL) [tubes][vials][applicators][pipettes]]

[0.027 fl oz (0.8 mL) [tubes][vials][applicators][pipettes]]

ACCEPTED

Feb 03, 2016

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 2517-173

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[ABNs]

[SENTRY® Vet for Cats Imidacloprid]
[SENTRY® Vet Advanced Flea for Cats]
[SENTRY® Vet FleaGuard for Cats]
[SENTRY® Vet Vantage for Cats]
[SENTRY® Vet Flea Vantage for Cats]
[SENTRY® Advanced for Cats Imidacloprid]
[SENTRY® Advanced FleaGuard for Cats]
[SENTRY® Advanced Vantage for Cats]
[SENTRY® Advanced Flea Vantage for Cats]
[SENTRY® Advanced VetSpot for Cats]
[PetArmor® Vantage for Cats]
[PetArmor® Advant for Cats]
[PetArmor® FleaGuard for Cats]
[PetArmor® Advanced for Cats]
[PetArmor® Flea Vantage for Cats]
[PetArmor® Adv Flea for Cats]
[PetArmor® Adv.Flea for Cats]
[PetArmor® AdVet for Cats]

[Begin Optional Active Ingredient Reference Statements]

{Note to Reviewer – the following is an example statement:

Contains imidacloprid, the active ingredient used in Advantage® 9 Topical Solution*

*[This product is not manufactured by Bayer Healthcare LLC, the makers of Advantage® 9 Topical Solution] [OR] [Advantage® 9 Topical Solution is a registered trademark of Bayer Healthcare LLC]}

[Brand Name] [This product] contains [imidacloprid,] the active ingredient used in
[Advantage® 9 Topical Solution] [Advantage® for Small Cats] [DefenseCare Flea Protection
Small Cat] [Advantage® TM 9 (Imidacloprid) Topical Solution].
{OR}

[Advantage® 18 Topical Solution] [Advantage® for Large Cats] [DefenseCare Flea Protection
Large Cat] [DefenseCare Flea Protection Large Cats] [Advantage® 18 (Imidacloprid) Topical
Solution].

*

{Note to reviewer: Text for footnote statement one}

*[Brand Name][This product] is not manufactured or distributed by Bayer Healthcare
LLC, the makers of

[Advantage® 9 Topical Solution] [Advantage® for Small Cats] [DefenseCare Flea Protection
Small Cat] [Advantage® TM 9 (Imidacloprid) Topical Solution].

{OR}

[Advantage® 18 Topical Solution] [Advantage® for Large Cats] [DefenseCare Flea Protection
Large Cat] [DefenseCare Flea Protection Large Cats] [Advantage® 18 (Imidacloprid) Topical
Solution].]

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{Note to reviewer: Text for footnote statement one}

*[*Advantage® 9 Topical Solution] [Advantage® for Small Cats] [DefenseCare Flea Protection Small Cat] [Advantage® TM 9 (Imidacloprid) Topical Solution]*

{OR}

[Advantage® 18 Topical Solution] [Advantage® for Large Cats] [DefenseCare Flea Protection Large Cat] [DefenseCare Flea Protection Large Cats] [Advantage® 18 (Imidacloprid) Topical Solution]

is a registered trademark of Bayer Healthcare LLC.]

[End Optional Active Ingredient Reference Statements]

[Fleas]

[Prevents further flea infestation for up to [[four][4] weeks][1 month] with one treatment]

[Prevents further flea infestation for up to [[four][4] weeks][1 month] with one application]

[Brand Name] Prevents further flea infestation for [four][4] weeks][1 month]

[Kills fleas within 12 hours [of application] on cats]

[Kills reinfesting fleas within 2 hours]

[Kills [adult] fleas before they lay eggs]

[[Brand Name][This product] kills fleas and may reduce the incidence of a hypersensitivity skin disorder called flea allergy dermatitis (FAD), which may be caused by the feeding activity of fleas on cats.]

[Apply monthly [for optimal flea control]]

[Apply monthly [to control and prevent fleas]]

[Kills fleas]

[Kill fleas within 12 hours, continues to kill for up to 4 weeks]

[Kills fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation]

[Kills fleas, which may be a source of flea allergy dermatitis, in 12 hours]]

[Stops and prevents infestation of listed pests for 4 weeks]

[Use [of Brand Name][of this product] kills fleas and may reduce incidence of flea bite hypersensitivity [and][or] [flea allergy dermatitis] [FAD]]

[Use [of Brand Name][of this product] kills fleas and may reduce incidence of [flea bite hypersensitivity] [and][or] flea allergy dermatitis [FAD]]

[Monthly treatment [with Brand Name][with this product] kills fleas and may reduce incidence of [flea bite hypersensitivity] [and][or] flea allergy dermatitis [FAD]]

[Monthly treatment [with Brand Name][with this product] kills fleas and may reduce incidence of flea bite hypersensitivity [and][or] [flea allergy dermatitis] [FAD]]

[Active against fleas]

[Kills fleas on [kittens and] cats]

[[Brand Name] Offers protection against fleas]

[Flea control for cats and kittens over 8 weeks [old][of age and 2 lbs]

[Flea control for cats and kittens 8 weeks [of age] or older and 2 lbs]

[Kills fleas within 12 hours on cats [and prevents further infestations for [up to] [[4][four] weeks][[1][one][a] month]]

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[All Others]

[Apply to [cats and] kittens over 8 weeks old and 2 lbs]

[Apply to [cats and] kittens 8 weeks or older and 2 lbs]

[SENTRY®]

[PetArmor®]

[[Sergeant's] Caring For Your Pets Since 1868]

[Formulated for Cats and Kittens Over 8 Weeks [Old][of Age] and 2 lbs]

[Formulated for Cats and Kittens 8 Weeks [of Age] or Older and 2 lbs]

[Cats and Kittens over 8 weeks [old][of age] and 2 lbs]

[Cats and Kittens 8 weeks [of age] or older and 2 lbs]

[Use only on kittens over 8 weeks [old][of age] and 2 lbs]

[Use only on kittens 8 weeks [of age] or older and 2 lbs]

[The Only Monthly Flea Protection You Need For Your Cat[s] When Applied Monthly!]

[Convenient]

[Easy application]

[Easy to apply product]

[Easy to Use [Application]]

[One Step Hassle Free Protection!]

[Waterproof]

[Remains effective, even after [bathing,][shampooing,] swimming, or exposure to sunlight

[and][or] [rain]]

[Remains effective, even after [bathing,][shampooing,] water immersion, or exposure to

[sunlight] [and][or] rain]

[Once a month treatment]

[Apply once every [4 weeks] [month] [30 days]!]

[4 Week Dose!] [1 Month Dose!] [30 Day Dose!]

[For year-round protection, apply [Brand Name][this product] monthly]

[One tube [vial][pipette]] [1 Month Supply]

[Two tubes [vials][pipettes]] [2 Month Supply]

[Three tubes [vials][pipettes]] [3 Month Supply]

[Four tubes [vials][pipettes]] [4 Month Supply]

[Five tubes [vials][pipettes]] [5 Month Supply]

[Six tubes [vials][pipettes]] [6 Month Supply]

[9 tubes [vials][pipettes]] [9 Month Supply]

[12 tubes [vials][pipettes]] [12 Month Supply]

[24 tubes [vials][pipettes]] [24 Month Supply]

[Direct to skin [tube][vial][applicator][pipette]]

[Easy to Use] [tube][vial][applicator][pipette]

[No-mess [open] [tube][vial][applicator][pipette]]

[Clip-tip design [tube][vial][applicator][pipette][!]]

{END – FRONT PANEL}

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BACK PANEL/SIDE PANEL

Cats Spot On Imidacloprid

[The active ingredient in [Brand Name][this product] is [imidacloprid,] formulated for control of fleas on cats.] [[Brand Name][This product] kills fleas within 12 hours and prevents further flea infestations for [up to] [[4][four]weeks][1][one] month][30 days].]

READ ENTIRE LABEL BEFORE EACH USE.

USE ONLY ON CATS AND KITTENS 8 WEEKS OF AGE OR OLDER.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. WARNING. Causes substantial but temporary eye injury.

Harmful if swallowed. Harmful if absorbed through the skin. Avoid contact with skin. Do not get in eyes or on clothing. Wash hands after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS. For external use on cats only. Individual sensitivities, while rare, may occur after using ANY pesticide product for cats. Do not treat your cat with more than one pesticide product at a time. Over dosing your cat can result in serious illness and even death. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing cats.

FIRST AID	
If In Eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If Swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If on Skin or Clothing	<ul style="list-style-type: none">• Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-781-4738 for emergency medical treatment information.	
NOTE TO PHYSICIAN	
Treat the patient symptomatically.	

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DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. TO PREVENT HARM TO YOU AND YOUR CAT, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

Restrictions:

- **DO NOT ALLOW CHILDREN TO APPLY PRODUCT.**
- Do not use on animals other than cats.
- Do not allow your cat to ingest this product.
- Do not reapply for [[four][4] weeks][30 days].
- Do not use on kittens under 8 weeks of age. Do not apply to cats weighing less than 2[9] lbs.
- Use entire contents of tube[vial][applicator][pipette] on each cat. Do not split one tube[vial][applicator][pipette] between two cats. Do not use multiple tube[vial][applicator][pipette]s on one cat.
- Weigh your cat to be sure you are applying the right dose formulated for the weight of your cat.
- Separate the treated cat from all other cats and dogs for 24 hours after treatment has been applied.
- Do not have contact or allow children to have contact with the treated area until completely dry.

{Side Effects box to be located on label on the lower right hand side of the back panel}

Side Effects: Monitor your cat after application. [Some cats may experience temporary startle effects when any product is applied.] Cats may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe your cat with a mild soap and rinse with large amounts of water. If these or other side effects occur, consult your veterinarian or call 1-800-781-4738. If your cat has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your cat and continue to monitor your cat for the next 24 hours.

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{OUTER PACKAGING}

How to Open:

1. Remove product tube[s][vial[s]][applicator[s]][pipette[s]] from the package.
2. Separate one tube[vial][applicator][pipette] from the others. Hold the tube[vial][applicator][pipette] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply:

1. Hold cat with one hand and use the other hand to apply the solution.
2. Invert the tube[vial][applicator][pipette] and use the narrow end to part the cat's hair.
3. Squeeze tube[vial][applicator][pipette] firmly to apply all of the solution [on][to] the cat's skin as a spot between the shoulder blades.

{For cartons containing 0.4 mL (0.014 fl oz) applicator tubes}

Only For Cats Weighing 2[-][to] 9 lbs. Do not apply to cats weighing less than 2 lbs.

[including small cats or kittens, only 8 weeks or older] Apply one

tube[vial][applicator][pipette] 0.4 mL (0.014 fl oz) directly to skin as a spot between the shoulder blades. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat.

{For cartons containing 0.8 mL (0.027 fl oz) applicator tube}

Only For Cats Weighing Over 9 lbs. Do not apply to cats weighing less than 9 lbs. Do not

use more than one [tube][vial][applicator][pipette] on cats greater than 9 lbs. Apply one

tube[vial][applicator][pipette] 0.8 mL (0.027 fl oz) directly to skin as a spot between the shoulder blades. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat.

FREQUENCY OF APPLICATION

[Use [Brand Name {or} this product] monthly for control of flea[s] [infestations].]

[[Studies show that] [Brand Name {or} This product] kills fleas within 12 hours of application and [lasts {or} protects] [for [up to] [[four][4] weeks][30 days][one month].]

[[Brand Name {or} This product] kills reinfesting fleas within [2][two] hours and prevents further infestations of fleas [for [up to] [[four][4] weeks][30 days][one month]].]

[If your cat is at high risk for flea reinfestation [,or in a highly infested environment], apply monthly.]

[Apply monthly for optimal flea control.]

[[Brand Name {or} This product] is waterproof and remains effective, even after water immersion or exposure to sunlight [and][or] [rain].]

[Allow treated area to dry thoroughly.]

{[How to Apply – May contain graphics illustrating product use, e.g., cat with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling. Please refer to the following optional graphics.]}



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STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove [tube][vial][applicator][pipette] from pack until ready to use. Store in a cool (below 77°F/[]/[25°C]), dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

CONTAINER DISPOSAL: **If empty:** Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[WARRANTY

Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. The directions for use of this product are believed to adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer. Sergeant's is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Sergeant's, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: [Sergeant's][SENTRY][PetArmor®] Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

[Satisfaction Guaranteed. If you are not satisfied, we will make it right with a replacement or refund.]

In Case of Emergency, call: 1-800-781-4738
Non-Emergency, call: 1-800-224-PETS (7387)

[Coupon(s) inside or on outside of box]
[Made in USA with Global Materials]

[Distributed by:] [Manufactured by:]
Sergeant's Pet Care Products, Inc.
Omaha, NE 68138-3710

EPA Reg. No. 2517-RTG
EPA Est. No. XXXXX-XX-XX
[BAR CODE AREA]

{END - BACK/SIDE PANEL}

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{START – ADDITIONAL OPTIONAL PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT PACKAGE OR INSERT}

[Clip. Part. Squeeze.]

Easier-than-ever applicator lets you *clip* the tip, *part* the fur and *apply* directly to the skin – putting proven flea protection where it needs to be.]

[Application Instructions]

How to Open:

1. Remove product tube[s][vial[s]][applicator[s]][pipette[s]] from the package.
2. Separate one tube[vial][applicator][pipette] from the others. Hold the tube[vial][applicator][pipette] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply:

1. Hold cat with one hand and use the other hand to apply the solution.
2. Invert the tube[vial][applicator][pipette] and use the narrow end to part the cat's hair.
3. Squeeze tube[vial][applicator][pipette] firmly to apply all of the solution [on][to] the cat's skin as a spot between the shoulder blades.

[Look at the Label [Easy] 6 Step [Easy] [Spot On] [Squeeze-On] [Topical] Checklist]

- [1] Read the label completely and follow directions
- [2] Weigh your cat
- [3] Do NOT use dog products on cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals after treatment [application] to avoid chance of ingestion
- [6] Do NOT split tube[vial][applicator][pipette] between cats][and use the ENTIRE [tube][vial][applicator][pipette] contents]

[Brand Name][This product]

[Monthly reminder card]

[1][2][3][4][5][6][12][24][Month [Treatment] [Application] Tracker][Carecard]

[For year round protection apply [Brand Name][this product] monthly.]

[Cat's Name (Empty blank for owner to fill in name)]

[Cat's Weight (Empty blank for owner to fill in name)]

[First][1st] [Second][2nd] [Third][3rd] [Fourth][4th] [Fifth][5th] [Sixth][6th] [Seventh][7th]

[Eighth][8th] [Ninth][9th] [Tenth][10th] [Eleventh][11th] [Twelfth][12th]

[Dose] [Treatment] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)]

[Application Date] [Date of Application]

[Calendar stickers with [Brand Name]

[Place stickers on your calendar as a reminder to reapply [Brand Name][this product] in 30 days.]

[Monthly Application Reminder Magnet (image of reminder magnet)]

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[Place sticker on your calendar [or refrigerator] to remind yourself to apply [Brand Name][this product] to your cat]





[33% More Free]

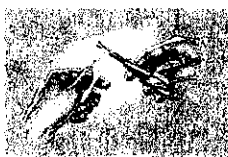
[Bonus Size]

[Buy 3 get 1 free]

[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days, the reminder light will blink, reminding you to reapply [Brand Name][this product]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

[Each optional graphic below may or may not appear anywhere on the finished label]

	Adult Flea	
	Fleas	



**MADE IN THE
USA**
WITH GLOBAL MATERIALS

*Refund or replacement of product {text footnoted to satisfaction guaranteed graphic}

{END – ADDITIONAL OPTIONAL PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT PACKAGE OR INSERT}

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TUBE/VIAL LABEL

**Cats Spot On
Imidacloprid**

{Front Label}

{Back Label}

[Brand Name (for Cats)] X-Y lbs. ≥8 wks Imidacloprid 9.10% 0.014 fl oz (or) 0.027 fl oz {label code}	KEEP OUT OF REACH OF CHILDREN WARNING: Read directions and precautions on package. Use scissors to open. EPA REG. No. 2517-RTG {label code}
--	--

{EPA REG No may be on either the front or back label}

{label code refers to Sergeant's product code number assigned to each product}

{END – TUBE/VIAL LABEL}

Kumar, Rita

From: Carrie Daniels <cdaniels@exponent.com>
Sent: Friday, January 15, 2016 12:06 PM
To: Kumar, Rita
Cc: James Messina; Eagle, Venus
Subject: 2517-RTG
Attachments: 2517-RTG Revised Label 1-15-16 clean.docx; 2517-RTG Revised Label 1-15-16 track.docx

Dear Rita,

Following our conversation this morning, I have attached the revised product label for Sergeants pending product 2517-RTG (track changes and clean). As we discussed, the following changes have been made:

- On the front vial label, the weight range is not optional.
- On the back vial label, the referral statement reads: "Read directions and precautions on package."
- The "Made in the USA" graphic is not on the clean copy, however, we have included the "Made in the USA with Global Materials" graphic as you indicated this was acceptable. I have also included the optional statement "Made in the USA with Global Materials" on page 9 of the track changes label.
- The note to reviewer for the footnote to the Satisfaction Guaranteed graphic was revised to read "{text footnoted to satisfaction guaranteed graphic}" to make is clear that this footnote will accompany the graphic.

Please do not hesitate to call me if you have any questions regarding this label and the changes as discussed.

Sincerely,
Carrie

Carrie Daniels
Senior Managing Regulatory Consultant
Exponent, Inc.
202-772-4916

Draft 1/13/16
Revisions needed (same as 2517-RTU),
Called Carrie,

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FRONT PANEL

Cats Spot On Imidacloprid

[Optional text appears in brackets/parenthesis – the final label may include some or all of the optional text on front, back or side label panels]

Sergeant's® 9.1% Imidacloprid Spot On for Cats

{Market Label-the word Cat will be at least 40-75% in height of the largest letter in the primary brand name.}

{Market Label-a large clear picture of a cat in the respective weight range will be on the front panel of the label.}

{One of the following statements will appear on appropriate weight band market label front panel as required per Agency's pet spot-on mitigation measures:}

For use ONLY on cats [[&][and] kittens] [weighing] 2 [-][to] 9 lbs. and over 8 weeks [old][of age] {0.4 ml size package}

For use ONLY on cats [[&][and] kittens] [weighing] 2 [-][to] 9 lbs. and 8 weeks [of age] or older {0.4 ml size package}

For use ONLY on cats [[&][and] kittens] [weighing] [more than][over][>] 9 lbs. and over 8 weeks [old][of age] {0.8 ml size package}

For use ONLY on cats [[&][and] kittens] [weighing] [more than][over][>] 9 lbs. and 8 weeks [of age] or older {0.8 ml size package}

ONLY for cats [[&][and] kittens] over 8 weeks [old][of age] and [weighing] 2 [-][to] 9 lbs. {0.4 ml size package}

ONLY for cats [[&][and] kittens] 8 weeks [of age] or older and [weighing] 2 [-][to] 9 lbs. {0.4 ml size package}

ONLY for cats [[&][and] kittens] over 8 weeks [old][of age] and [weighing] [more than][over][>] 9 lbs. {0.8 ml size package}

ONLY for cats [[&][and] kittens] 8 weeks [of age] or older and [weighing] [more than][over][>] 9 lbs. {0.8 ml size package}

ACTIVE INGREDIENT:

Imidacloprid9.10%

OTHER INGREDIENTS:90.90%

[TOTAL100.00%]

KEEP OUT OF REACH OF CHILDREN WARNING

See [Back][or][Side][Label[s]][Panel[s]] for Additional Precautionary Statements

NET CONTENT: X fl oz [Y – X fl oz applicators]

[0.014 fl oz (0.4 mL) [tubes][vials][applicators][pipettes]]

[0.027 fl oz (0.8 mL) [tubes][vials][applicators][pipettes]]

epa.gov/pets

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[ABNs]

[SENTRY® Vet for Cats Imidacloprid]

[SENTRY® Vet Advanced Flea for Cats]

[SENTRY® Vet FleaGuard for Cats]

[SENTRY® Vet Vantage for Cats]

[SENTRY® Vet Flea Vantage for Cats]

[SENTRY® Advanced for Cats Imidacloprid]

[SENTRY® Advanced FleaGuard for Cats]

[SENTRY® Advanced Vantage for Cats]

[SENTRY® Advanced Flea Vantage for Cats]

[SENTRY® Advanced VetSpot for Cats]

[PetArmor® Vantage for Cats]

[PetArmor® Advant for Cats]

[PetArmor® FleaGuard for Cats]

[PetArmor® Advanced for Cats]

[PetArmor® Flea Vantage for Cats]

[PetArmor® Adv Flea for Cats]

[PetArmor® Adv.Flea for Cats]

[PetArmor® AdVet for Cats]

[Begin Optional Active Ingredient Reference Statements]

[Note to Reviewer – the following is an example statement:]

Contains imidacloprid, the active ingredient used in Advantage® 9 Topical Solution*

*[This product is not manufactured by Bayer Healthcare LLC, the makers of Advantage® 9 Topical Solution] [OR] [Advantage® 9 Topical Solution is a registered trademark of Bayer Healthcare LLC]

[Contains imidacloprid, the same active ingredient used in

[OR]

[Contains the same active ingredient used in

[OR]

[Brand Name] [This product] contains [imidacloprid, the same active ingredient used in

[OR]

[Advantage® 9 Topical Solution] [Advantage® for Small Cats] [DefenseCare Flea Protection Small Cat] [Advantage® TM 9 (Imidacloprid) Topical Solution].*]

[OR]

[Contains imidacloprid, the same active ingredient used in [Advantage® 18 Topical Solution] [Advantage® for Large Cats] [DefenseCare Flea Protection Large Cat] [DefenseCare Flea Protection Large Cats] [Advantage® 18 (Imidacloprid) Topical Solution].

*)

[Note to reviewer: Text for footnote statement one]

.[*][Brand Name][This product] is not manufactured or distributed by Bayer Healthcare LLC, the makers of

[Advantage® 9 Topical Solution] [Advantage® for Small Cats] [DefenseCare Flea Protection Small Cat] [Advantage® TM 9 (Imidacloprid) Topical Solution].*]

[OR]

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~~[Contains imidacloprid, the same active ingredient used in Advantage® 18 Topical Solution] [Advantage® for Large Cats] [DefenseCare Flea Protection Large Cat] [DefenseCare Flea Protection Large Cats] [Advantage® 18 (Imidacloprid) Topical Solution].~~

~~*/~~

~~[OR]~~

~~[Note to reviewer: Text for footnote statement one]~~

~~[*Advantage® 9 Topical Solution] [Advantage® for Small Cats] [DefenseCare Flea Protection Small Cat] [Advantage® TM 9 (Imidacloprid) Topical Solution] is a registered trademark of Bayer Healthcare LLC.]~~

~~[OR]~~

~~[*Advantage® 18 Topical Solution] [Advantage® for Large Cats] [DefenseCare Flea Protection Large Cat] [DefenseCare Flea Protection Large Cats] [Advantage® 18 (Imidacloprid) Topical Solution]~~

~~is a registered trademark of Bayer Healthcare LLC.]~~

[End Optional Active Ingredient Reference Statements]

[Fleas]

[Prevents further flea infestation for up to [[four][4] weeks][1 month] with one treatment]

[Prevents further flea infestation for up to [[four][4] weeks][1 month] with one application]

[Brand Name] Prevents further flea infestation for [four][4] weeks][1 month]

[Kills fleas within 12 hours [of application] on cats]

[Kills reinfesting fleas within 2 hours]

[Kills [adult] fleas before they lay eggs]

[[Brand Name][This product] kills fleas and may reduce the incidence of a hypersensitivity skin disorder called flea allergy dermatitis (FAD), which may be caused by the feeding activity of fleas on cats.]

~~[Kills flea larvae in cat's environment following contact with treated cat]~~

[Apply monthly [for optimal flea control]]

[Apply monthly [to control and prevent fleas]]

[Kills fleas]

[Kill fleas within 12 hours, continues to kill for up to 4 weeks]

[Kills fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation]

[Kills fleas, which may be a source of flea allergy dermatitis, in 12 hours]

[Stops and prevents infestation of listed pests for 4 weeks]

[Use [of Brand Name][of this product] kills fleas and may reduce incidence of flea bite hypersensitivity [and][or] [flea allergy dermatitis] [FAD]]

[Use [of Brand Name][of this product] kills fleas and may reduce incidence of [flea bite hypersensitivity] [and][or] flea allergy dermatitis [FAD]]

[Monthly treatment [with Brand Name][with this product] kills fleas and may reduce incidence of [flea bite hypersensitivity] [and][or] flea allergy dermatitis [FAD]]

[Monthly treatment [with Brand Name][with this product] kills fleas and may reduce incidence of flea bite hypersensitivity [and][or] [flea allergy dermatitis] [FAD]]

~~[Flea protection]~~

[Active against fleas]

[Kills fleas on [kittens and] cats]

[[Brand Name] Offers protection against fleas]

[Flea control for cats and kittens ~~over 8 weeks [old]~~ [of age and 2 lbs]]

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[Flea control for cats and kittens {8 weeks [of age] or older and 2 lbs}]

[Kills fleas within 12 hours on cats [and prevents further infestations for [up to] [[4][four] weeks][[1][one][a] month]]]

[All Others]

[Apply to [cats and] kittens over 8 weeks old and 2 lbs] _____

[Apply to [cats and] kittens 8 weeks or older and 2 lbs]

[SENTRY®]

[PetArmor®]

[[Sergeant's] Caring For Your Pets Since 1868]

[Specially-Formulated for Cats and Kittens {Over 8 Weeks [Old][of Age] and 2 lbs}]

[Specially-Formulated for Cats and Kittens {8 Weeks [of Age] or Older and 2 lbs}]

[Cats and Kittens {over 8 weeks [old][of age] and 2 lbs}]

[Cats and Kittens {8 weeks [of age] or older and 2 lbs}]

[Use only on kittens {over 8 weeks [old][of age] and 2 lbs}]

[Use only on kittens {8 weeks [of age] or older and 2 lbs}]

[The Only Monthly Flea Protection You Need For Your Cat[s] When Applied Monthly!]

[Convenient]

[Easy application]

[Easy to apply product]

[Easy to Use [Application]]

[One Step Hassle Free Protection!]

[Waterproof]

[Remains effective, even after [bathing,][shampooing,] swimming, or exposure to sunlight

[and][or] [rain]]

[Remains effective, even after [bathing,][shampooing,] water immersion, or exposure to

[sunlight] [and][or] rain]

[Once a month treatment]

[Apply once every [4 weeks] [month] [30 days]!]

[4 Week Dose!] [1 Month Dose!] [30 Day Dose!]

[For year-round protection, apply [Brand Name][this product] monthly]

[[Best if used year-round!]

[X tubes [vial][pipettes]]Applications] _____ [X-Week Supply] _____ [X Month Supply]

[One tube [vial][pipette]]Application] _____ [4-Week Supply] _____ [1 Month Supply]

[Two tubes [vials][pipettes]]Applications] _____ [8-Week Supply] _____ [2 Month Supply]

[Three tubes [vials][pipettes]]Applications] _____ [12-Week Supply] _____ [3 Month Supply]

[Four tubes [vials][pipettes]]Applications] _____ [16-Week Supply] _____ [4 Month Supply]

[Five tubes [vials][pipettes]]Applications] _____ [20-Week Supply] _____ [5 Month Supply]

[Six tubes [vials][pipettes]]Applications] _____ [24-Week Supply] _____ [6 Month Supply]

[9 tubes [vials][pipettes]]Applications] _____ [36-Week Supply] _____ [9 Month Supply]

[12 tubes [vials][pipettes]]Applications] _____ [52-Week Supply] _____ [12 Month Supply]

[24 tubes [vials][pipettes]]Applications] _____ [104-Week Supply] _____ [24 Month Supply]

[[for] Small Cat[s] [2 to 9 lbs.]]

[[for] Large Cat[s] [Over 9 lbs.]]

[Direct to skin [tube][vial][applicator][pipette]]

[Easy to Use] [tube][vial][applicator][pipette]

[Clean cut [open] [tube][vial][applicator][pipette]]

[No-mess [open] [tube][vial][applicator][pipette]]

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[Clip-tip design [tube][vial][applicator][pipette][!]]

{END – FRONT PANEL}

BACK PANEL/SIDE PANEL OR INSERT

Cats Spot On

Imidacloprid

[The active ingredient in [Brand Name][this product] is [imidacloprid,] formulated for fast-acting
[and long-lasting] control of fleas on cats.] [[Brand Name][This product] kills fleas within 12
hours and prevents further flea infestations for [up to] [[4][four]weeks][1][one] month][30 days].]

READ ENTIRE LABEL BEFORE EACH USE.

USE ONLY ON CATS AND KITTENS 8 WEEKS OF AGE OR OLDER.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. WARNING. Causes substantial but temporary eye injury. ~~Do not get in eyes or on clothing.~~ Harmful if swallowed. Harmful if absorbed through the skin. Avoid contact with skin. ~~Do not get in eyes or on clothing.~~ Wash hands after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. ~~thoroughly with soap and warm water after handling.~~

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HAZARDS TO DOMESTIC ANIMALS. For external use on cats only. Individual sensitivities, while rare, may occur after using ANY pesticide product for cats. Do not treat your cat with more than one pesticide product at a time. Over dosing your cat can result in serious illness and even death. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing cats.

FIRST AID

If In Eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If Swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If on Skin or Clothing	<ul style="list-style-type: none">• Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-781-4738 for emergency medical treatment information.

NOTE TO PHYSICIAN

Treat the patient symptomatically.

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DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. ~~DO NOT ALLOW CHILDREN TO APPLY PRODUCT.~~ TO PREVENT HARM TO YOU AND YOUR CAT, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

Restrictions:

- **DO NOT ALLOW CHILDREN TO APPLY PRODUCT.**
- Do not use on animals other than cats.
- Do not allow your cat to ingest this product.
- Do not reapply for [four][4] weeks/[30 days].
- Do not use on kittens under 8 weeks of age. Do not apply to cats weighing less than 2[9] lbs.
- Use entire contents of tube[vial][applicator][pipette] on each cat. Do not split one tube[vial][applicator][pipette] between two cats. Do not use multiple tube[vial][applicator][pipette]s on one cat.
- Weigh your cat to be sure you are applying the right dose formulated for the weight of your cat.
- Separate the treated cat from all other cats and dogs for 24 hours after treatment has been applied.
- Do not have contact or allow children to have contact with the treated area until completely dry.

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{Side Effects box to be located on label on the lower right hand side of the back panel}

Side Effects: Monitor your cat after application. [Some cats may experience temporary startle effects when any product is applied.] Cats may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe your cat with a mild soap and rinse with large amounts of water. If these or other side effects occur, consult your veterinarian or call 1-800-781-4738. If your cat has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your cat and continue to monitor your cat for the next 24 hours.

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{OUTER PACKAGING}

How to Open:

1. Remove product tube[s]{vial[s]}[applicator[s]][pipette[s]] from the package.
2. Separate one tube[vial][applicator][pipette] from the others. Hold the tube[vial][applicator][pipette] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to open: Remove product {tube[s]}{vial[s]}[applicator[s]][pipette[s]] from the package. [Separate one {tube}[vial][applicator][pipette] from the others.] Hold the {tube}[vial][applicator][pipette] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply:

1. Hold cat with one hand and use the other hand to apply the solution.
2. Invert the tube[vial][applicator][pipette] and use the narrow end to part the cat's hair.
3. Squeeze tube[vial][applicator][pipette] firmly to apply all of the solution [on]to the cat's skin as a spot between the shoulder blades.

{For cartons containing 0.4 mL (0.014 fl oz) applicator tubes}

Only For Cats Weighing 2-[]to 9 lbs. Do not apply to cats weighing less than 2 lbs.

[including small cats or kittens, only 8 weeks or older] Apply one

{tube}[vial][applicator][pipette] 0.4 mL (0.014 fl oz) {directly to skin} as a spot between the shoulder blades. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat.

{For cartons containing 0.8 mL (0.027 fl oz) applicator tube}

Only For Cats Weighing Over 9 lbs. Do not apply to cats weighing less than 9 lbs. Do not

use more than one {tube}[vial][applicator][pipette] on cats greater than 9 lbs. Apply one

{tube}[vial][applicator][pipette] 0.8 mL (0.027 fl oz) {directly to skin} as a spot between the shoulder blades. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat.

FREQUENCY OF APPLICATION

[Use {Brand Name} {or} this product] monthly for control of flea[s] [infestations].]

[[Studies show that] {Brand Name} {or} This product] kills fleas within 12 hours of application and [lasts {or} protects] [for [up to] [[four][4] weeks][30 days][one month].]

[[{Brand Name} {or} This product] kills reinfesting fleas within [2][two] hours and prevents further infestations of fleas [for [up to] [[four][4] weeks][30 days][one month]].]

[If your cat is at high risk for flea reinfestation [,or in a highly infested environment], apply monthly.]

[Apply monthly for optimal flea control.]

[[{Brand Name} {or} This product] is waterproof and remains effective, even after water immersion or exposure to sunlight [and][or] [rain].]

[Allow treated area to dry thoroughly.]

[Do not reapply for [[four][4] weeks][30 days].]

4 How to Apply May contain graphics illustrating product use, e.g., cat with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling. Please refer to the following optional graphics B.



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STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove [tube][vial][applicator][pipette] from pack until ready to use. Store in a cool (below 77°F/[25°C]), dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

CONTAINER DISPOSAL: If empty: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

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[WARRANTY

Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. The directions for use of this product are believed to adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer. Sergeant's is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Sergeant's, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: [Sergeant's][SENTRY][PetArmor®] Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

[Satisfaction Guaranteed_]If you are not satisfied, we will make it right with a replacement or refund.]

In Case of Emergency, call: 1-800-781-4738
Non-Emergency, call: 1-800-224-PETS (7387)

[Coupon(s) inside or on outside of box]
[Made in U.S.A.][with Global Materials]

[Distributed by:] [Manufactured by:]
Sergeant's Pet Care Products, Inc.
Omaha, NE 68138-3710

EPA Reg. No. 2517-RTG
EPA Est. No. XXXXX-XX-XX
[BAR CODE AREA]

{END - BACK/SIDE PANEL OR INSERT}

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{START - ADDITIONAL OPTIONAL PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT PACKAGE OR INSERT}

[How to Apply - May contain graphics illustrating product use, e.g., cat with a drop falling onto its neck from a tube/vial on front, sides or back carton label and/or applicator labeling. Refer to optional graphics section at end of label for all possible graphic options.]

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[Clip. Part. Squeeze.]

Easier-than-ever applicator lets you *clip* the tip, *part* the fur and *apply* directly to the skin – putting proven flea protection where it needs to be.]

[Application Instructions]

How to Open:

1. Remove product tube[s][vial[s]][applicator[s]][pipette[s]] from the package.
1. Separate one tube[vial][applicator][pipette] from the others. Hold the tube[vial][applicator][pipette] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply:

1. Invert tube[vial][applicator][pipette] over cat and use open end to part cat's hair.
2. Apply contents of one tube[vial][applicator][pipette] of [Brand Name] as a spot between the shoulder blades. Squeeze tube firmly to apply all of the solution to the cat's skin.

How to Open:

1. Remove product tube[s][vial[s]][applicator[s]][pipette[s]] from the package.
2. Separate one tube[vial][applicator][pipette] from the others. Hold the tube[vial][applicator][pipette] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

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How to Apply:

1. Hold cat with one hand and use the other hand to apply the solution.
2. Invert the tube[vial][applicator][pipette] and use the narrow end to part the cat's hair.
3. Squeeze tube[vial][applicator][pipette] firmly to apply all of the solution [on][to] the cat's skin as a spot between the shoulder blades.

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While holding the cat with one hand, use the other hand to apply the solution. Invert the [tube][vial][applicator][pipette] and use the narrow end to part the cat's hair. Apply contents of one [tube][vial][applicator][pipette] of [Brand Name] [this product] to the cat's skin, as directed below. When finished, wrap the [tube][vial][applicator][pipette] in paper and put into the trash. Only one [tube][vial][applicator][pipette] per treatment is needed.

[Look at the Label (Look at the Label icon) [Easy] 6 Step [Easy] [Spot On] [Squeeze-On] [Topical] Checklist]

- [1] Read the label completely and follow directions
- [2] Weigh your cat
- [3] Do NOT use dog products on cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals after treatment [application] to avoid chance of ingestion
- [6] Do NOT split tube[vial][applicator][pipette] between cats[and use the ENTIRE [tube][vial][applicator][pipette] contents]

Sergeant's® Master Label

1345 January/December 20165

Version 15.1

EPA Reg. No. 2517-RTG

Information in [] is optional.

Information in { } is note to reviewer.

Page 10 of 9

[Brand Name][This product]

[Monthly reminder card]

[1][2][3][4][5][6][12][24][Month [Treatment] [Application] Tracker][Carecard]

[For year round protection apply [Brand Name][this product] monthly.]

[Cat's Name (Empty blank for owner to fill in name)]

[Cat's Weight (Empty blank for owner to fill in name)]

[First][1st] [Second][2nd] [Third][3rd] [Fourth][4th] [Fifth][5th] [Sixth][6th] [Seventh][7th]

[Eighth][8th] [Ninth][9th] [Tenth][10th] [Eleventh][11th] [Twelfth][12th]

[Dose] [Treatment] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)

[Application Date] [Date of Application]

[Calendar stickers with [Brand Name]

[Place stickers on your calendar as a reminder to reapply [Brand Name][this product] in 30 days.]

[Monthly Application Reminder Magnet (image of reminder magnet)]

[Place sticker on your calendar [or refrigerator] to remind yourself to apply [Brand Name][this product] to your cat]







[33% More Free]

[Bonus Size]

[Buy 3 get 1 free]

[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days, the reminder light will blink, reminding you to reapply [Brand Name][this product]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

[Each optional graphic below may or may not appear anywhere on the finished label]

	Adult Flea	
	Fleas	
	Flea Larvae	



Sergeant's® Master Label

1315 January/December 20165

Version 15.1

EPA Reg. No. 2517-RTG

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Page 11 of 9

~~*Money back~~Refund or replacement of product {text footnoted to graphic}

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~~MADE IN THE
USA~~

MADE IN THE
USA
WITH GLOBAL MATERIALS

{END – ADDITIONAL OPTIONAL PACKAGE COPY OR FOLDED PANEL/FLAP OF
FRONT PACKAGE OR INSERT}

Sergeant's® Master Label

1345 January-December 20165

Version 15.1

EPA Reg. No. 2517-RTG

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Information in () is note to reviewer.

Page 12 of 9

TUBE/VIAL LABEL

**Cats Spot On
Imidacloprid**

{Front Label}

{Back Label}

[Brand Name (for Cats)]

[X-Y] lbs. ≥8 wks

Imidacloprid 9.10%

0.014 fl oz (or) 0.027 fl oz {label code}

KEEP OUT OF REACH OF CHILDREN

WARNING: Read directions and precautions
before using. Use scissors to open.

EPA REG. No. 2517-RTG {label code}

{EPA REG No may be on either the front or back label}

{label code refers to Sergeant's product code number assigned to each product}

{END – TUBE/VIAL LABEL}

Must have the referral statement

1-7-2016

Note To File

2517-RTG ~~2517~~
2517-RTU

1. Similarity Clinic required that this product be placed in child resistant packaging^(CRP). Since all acute toxicity data were cited, and the cited product is not in CRP, we decided to not require CRP for this ~~subject~~ product. This also applies to 2517-RTU.
2. Even though product chemistry review states that ~~all~~ the basic and all alternate formulations (1, 2 & 3) ~~data~~ are acceptable, we decided to only accept the ^{12/19/2014} alternate # 1, because the source product in alt. # 1
[REDACTED]
[REDACTED] This alt. # 1 was resubmitted as the new basic CSF dated 12/30/2015 by the registrant.

Product ingredient source information may be entitled to confidential treatment

From: James Messina <jmessina@exponent.com>
Sent: Tuesday, January 05, 2016 10:06 AM
To: Kumar, Rita
Cc: Benbow, Gene; Carrie Daniels; Lewis, Marianne; Eagle, Venus
Subject: RE: 2517-RTU and 2517-RTG
Attachments: 2518-RTU Basic CSF 12-30-15.pdf; 8570-27 Form Ex 2517-RTU imidacloprid.pdf; 2517-RTG Basic CSF 12-30-15.pdf; 8570-27 Form Ex 2517-RTG imidacloprid.pdf

Dear Rita,

Please find attached the updated forms and basic CSFs.

Please let me know if we have any issues related to timing. The PRIA clock ended on 12/10 and as I recall we entered a 30-day period to resolve the label comments. It is our intent to obtain the registrations and we do not want to have any issues related to timing. Please confirm this is not a concern. We have incorporated almost all of EPA's label comments and have noted the following (copy of 12/29 email to Gene):

Dear Gene,

Thank you for contacting me today regarding the two pending Sergeant's product labels. Please find attached the latest label submissions. I have also attached the labels as PDF's.

In your email today you noted the two following comments:

Upper weight limit for the larger package

We note that none of the other EPA approved product labels for imidacloprid containing spot-ons have an upper weight limit on the larger package. This includes the following EPA approved products: 2596-180, 2596-181, 2596-182, 2596-183, 11556-116, 11556-117, 11556-118, 11556-119, 11556-120, 11556-122, 11556-125, 11556-127, 11556-128, 11556-130.

We also note that EPA approved two recent imidacloprid (and PPF) spot-on registrations on December 17, 2015 under 91300-2 and 91300-3. Neither of these EPA approved labels contain an upper weight limit for the larger package. This is found on multiple pages for each of the approved labels:

1. 91300-2: page 1, 3, 5, 7
2. 91300-3: page 1, 3, 6

Based upon the EPA approvals an upper weight limit for the large size is not required.

Do not double-dose animals

This comment has already been addressed on the labels. The attached labels include the following statements (under restrictions):

- Use entire contents of tube[vial][applicator][pipette] on each cat. Do not split one tube[vial][applicator][pipette] between two cats. Do not use multiple tube[vial][applicator][pipette]s on one cat.
- Use entire contents of tube[vial][applicator][pipette] on each dog. Do not split one tube[vial][applicator][pipette] between two dogs. Do not use multiple tube[vial][applicator][pipette]s on one dog.

This language has been previously approved by EPA on other pet spot-on product labels and it addresses this language requirement.

Other EPA noted label comments

Please note, we have agreed to several label language changes on the attached labels; however, we note that EPA recently approved the same label language it required Sergeant's to change on the December 17, 2015 EPA approvals for 91300-2 and 91300-3. At this time, we request that EPA allow Sergeant's to have the same label claims as EPA approved for the products 91300-2 and 91300-3 noted below:

- No upper weight limit (addressed above)
- "Kills fleas (*Ctenocephalides* sp.) on your dog and in its environment" (Sergeant's was asked to remove this label claim)
- "Kills fleas on dogs within 12 hours to prevent infestations for [4 weeks][1 month]" (Sergeant's was required to add "further" to this statement and Promika was allowed to not state "further" in the claim)
- "Flea protection" (Sergeant's was required to delete the identical claim)

The only difference between these products is that the 91300 products contain the insect growth regulator (IGR) pyriproxyfen. This IGR does not have any effect on the noted label claims above. We request that EPA allow the same label claims on the Sergeant's labels. This will require us to send you updated labels to review.

I am out of the office this week but I can be reached at 301-908-1181 to discuss any of the information contained in this email or enclosures. I look forward to finalizing these labels with you.

I am available all day Thursday to discuss the label comments and questions above. Please let me know if we can schedule a call for 1:00 pm to discuss in more detail? If this time does not work for you, please propose a different time for a call on Thursday. Thanks.

Best Regards,

James Messina
Center Director and Principal Regulatory Consultant
Exponent, Inc.
Center for Chemical Regulation and Food Safety
1150 Connecticut Ave., NW, Suite 1100
Washington, DC 20036
O: 202.772.4932
M: 301.908.1181
jmessina@exponent.com

From: Kumar, Rita [mailto:Kumar.Rita@epa.gov]
Sent: Tuesday, January 05, 2016 9:03 AM
To: James Messina
Cc: Benbow, Gene; Carrie Daniels; Lewis, Marianne; Eagle, Venus
Subject: RE: 2517-RTU and 2517-RTG

Jim: I do want you to send me the CSF for the new basic with new date, and the formulator's exemption form with the same date. This will avoid confusion later on. Note that [REDACTED] is the only acceptable source of imidacloprid for these products.

I am on leave today, and may not be checking my e-mail until later. I will working at home on Thursday, and will review the label revisions. If you made all the changes that Venus and I asked for, there should not be a problem. Otherwise we may have to wait until next week when Venus will be back from vacation.

Regards,
Rita

Product ingredient source information may be entitled to confidential treatment

From: James Messina [<mailto:jmessina@exponent.com>]
Sent: Thursday, December 31, 2015 1:57 PM
To: Kumar, Rita <Kumar.Rita@epa.gov>
Cc: Benbow, Gene <Benbow.Gene@epa.gov>; Carrie Daniels <cdaniels@exponent.com>; Lewis, Marianne <Lewis.Marianne@epa.gov>; Eagle, Venus <Eagle.Venus@epa.gov>
Subject: RE: 2517-RTU and 2517-RTG

Rita,

Please find attached the updated formulators exemption form. We agree to drop the TGA1 sources: [REDACTED] and [REDACTED]. The only TGA1 source for imidacloprid we will use (including the appropriate CSF) is: [REDACTED]. Please confirm you do not want me to send CSF's for the acceptable formulation marking it as the basic.

Can we please plan to talk on Monday regarding the final label comments?

Best Regards,

James Messina
Center Director and Principal Regulatory Consultant
Exponent, Inc.
Center for Chemical Regulation and Food Safety
1150 Connecticut Ave., NW, Suite 1100
Washington, DC 20036
O: 202.772.4932
M: 301.908.1181
jmessina@exponent.com

From: Kumar, Rita [<mailto:Kumar.Rita@epa.gov>]
Sent: Thursday, December 31, 2015 12:40 PM
To: James Messina
Cc: Benbow, Gene; Carrie Daniels; Lewis, Marianne; Eagle, Venus
Subject: RE: 2517-RTU and 2517-RTG
Importance: High

Dear Jim: I am responding to the attachment that you sent with this last part of your e-mail trail below. This is only in reference to the two imidacloprid only products, 2517-RTU and -RTG.

In this attachment (which does not show in this response, you will have to refer to your e-mail dated 12/29 to Gene and Carrie), you proposed to submit a new basic CSF listing [REDACTED] as the imidacloprid TGA1 source, and asked if that will address the generic data issue with formulator's exemption.

You could do that while the PRIA submission was still open because we would need to send the new basic CSF it to our chemists for approval. We will not be able to do that now, because the PRIA submission has been closed for both products. However, I want to let you know that you already submitted alternate #1 (dated 12/19/2014) for both of these products that lists [REDACTED] as the source product. Since this source is [REDACTED] a formulator's exemption will satisfy the generic data requirements. This alternate #1 has been reviewed by our chemists and found to be acceptable, therefore we can label this as the basic CSF. You still need to send us a revised formulator's exemption form listing [REDACTED] as the only source product. All other CSFs will be unacceptable.

Please let us know in writing that this proposed solution is acceptable to you, and submit a revised formulator's exemption statement ASAP. I am here until 3 p.m. today.

Regards,

Rita

From: James Messina [<mailto:jmessina@exponent.com>]
Sent: Wednesday, December 30, 2015 10:58 AM
To: Eagle, Venus <Eagle.Venus@epa.gov>; Kumar, Rita <Kumar.Rita@epa.gov>
Cc: Benbow, Gene <Benbow.Gene@epa.gov>; Carrie Daniels <cdaniels@exponent.com>
Subject: FW: 2517-RTU and 2517-RTG

Dear Venus and Rita,

Can we please plan to talk on Monday or Tuesday regarding the final items for these two registrations. The text below provides label comments to discuss and the attached email addresses the TGA generic data requirements. Please review these and let me know when we can schedule a call to resolve the last few items. Many thanks.

Best Regards,

James Messina
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Center for Chemical Regulation and Food Safety
1150 Connecticut Ave., NW, Suite 1100
Washington, DC 20036
O: 202.772.4932
M: 301.908.1181
jmessina@exponent.com

From: Benbow, Gene [<mailto:Benbow.Gene@epa.gov>]
Sent: Tuesday, December 29, 2015 2:09 PM
To: James Messina
Cc: Carrie Daniels
Subject: RE: 2517-RTU and 2517-RTG

Hi Jim -- I appreciate the quick response. What I have in front of me are essentially some notes from Venus and a lot of back-and-forth you guys had with Rita. It sounds like you are now wanting to add *back* certain claims and also rearrange your sources from what she (Venus) indicated to me.

This is a bit too convoluted for me to jump in at the end and try to make sense of without Venus or Rita here. One of us will get back to you once Venus returns to the office –

Thanks,

Gene Benbow
Biologist, EPA
Invertebrate & Vertebrate Branch 3
Registration Division
<http://epa.gov/pesticides/>
703-347-0235

From: James Messina [<mailto:jmessina@exponent.com>]
Sent: Tuesday, December 29, 2015 11:55 AM
To: Benbow, Gene <Benbow.Gene@epa.gov>

Cc: Carrie Daniels <cdaniels@exponent.com>

Subject: RE: 2517-RTU and 2517-RTG

Dear Gene,

Thank you for contacting me today regarding the two pending Sergeant's product labels. Please find attached the latest label submissions. I have also attached the labels as PDF's.

In your email today you noted the two following comments:

Upper weight limit for the larger package

We note that none of the other EPA approved product labels for imidacloprid containing spot-ons have an upper weight limit on the larger package. This includes the following EPA approved products: 2596-180, 2596-181, 2596-182, 2596-183, 11556-116, 11556-117, 11556-118, 11556-119, 11556-120, 11556-122, 11556-125, 11556-127, 11556-128, 11556-130.

We also note that EPA approved two recent imidacloprid (and PPF) spot-on registrations on December 17, 2015 under 91300-2 and 91300-3. Neither of these EPA approved labels contain an upper weight limit for the larger package. This is found on multiple pages for each of the approved labels:

1. 91300-2: page 1, 3, 5, 7
2. 91300-3: page 1, 3, 6

Based upon the EPA approvals an upper weight limit for the large size is not required.

Do not double-dose animals

This comment has already been addressed on the labels. The attached labels include the following statements (under restrictions):

- Use entire contents of tube[vial][applicator][pipette] on each cat. Do not split one tube[vial][applicator][pipette] between two cats. Do not use multiple tube[vial][applicator][pipette]s on one cat.
- Use entire contents of tube[vial][applicator][pipette] on each dog. Do not split one tube[vial][applicator][pipette] between two dogs. Do not use multiple tube[vial][applicator][pipette]s on one dog.

This language has been previously approved by EPA on other pet spot-on product labels and it addresses this language requirement.

Other EPA noted label comments

Please note, we have agreed to several label language changes on the attached labels; however, we note that EPA recently approved the same label language it required Sergeant's to change on the December 17, 2015 EPA approvals for 91300-2 and 91300-3. At this time, we request that EPA allow Sergeant's to have the same label claims as EPA approved for the products 91300-2 and 91300-3 noted below:

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- "Kills fleas (Ctenocephalides sp.) on your dog and in its environment" (Sergeant's was asked to remove this label claim)
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The only difference between these products is that the 91300 products contain the insect growth regulator (IGR) pyriproxyfen. This IGR does not have any effect on the noted label claims above. We request that EPA allow the same label claims on the Sergeant's labels. This will require us to send you updated labels to review.

I am out of the office this week but I can be reached at 301-908-1181 to discuss any of the information contained in this email or enclosures. I look forward to finalizing these labels with you.

Best Regards,

James Messina
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Center for Chemical Regulation and Food Safety
1150 Connecticut Ave., NW, Suite 1100
Washington, DC 20036
O: 202.772.4932
M: 301.908.1181
jmessina@exponent.com

From: Benbow, Gene [<mailto:Benbow.Gene@epa.gov>]
Sent: Tuesday, December 29, 2015 7:35 AM
To: James Messina
Subject: 2517-RTU and 2517-RTG

Hi Jim,

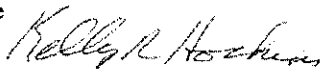
Rita is away from the office on use-or-lose leave (I think) so Venus is having me work these two product labels up in here absence. I have all the background (list of comments Rita sent you dated 12/4/15, etc.) and just need both labels from you in pdf format if possible. I can then do a final review and hopefully get these moving pretty quickly.

Venus mentioned that you guys were going to do a cite-all for the generic data on a revised matrix for companion animal use. Please send this to me as well if you would, by email if you prefer.

For label comments on 2517-RTG, the only one I see that appears to not have been captured in this email to you from Rita on 12/13/15 is the upper weight limit for the larger package (8 oz). The "do not double-dose animals...." text she was asking for if that rings a bell. I haven't reviewed -RTU yet.

Thanks,

Gene Benbow
Biologist, EPA
Invertebrate & Vertebrate Branch 3
Registration Division
<http://epa.gov/pesticides/>
703-347-0235

United States Environmental Protection Agency Washington, DC 20460 Formulator's Exemption Statement <i>(40 CFR 152.85)</i>		
Applicant's Name and Address Sergeant's Pet Care Products, Inc. 10077 South 134th Street Omaha, NE 68138-3710	EPA File Symbol/Registration Number 2517-RTG Product Name Sergeant's 9.1% Imidacloprid Spot On for Cats Date of Confidential Statement of Formula (EPA Form 8570-4) December 30, 2015	
As an authorized representative of the applicant for registration of the product identified above, I certify that:		
(1) This product contains the following active ingredient(s): Imidacloprid		
(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.		
(3) Indicate by checking (A) or (B) below which paragraph applies:		
<input checked="checked" type="checkbox"/> (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1)		
OR		
<input type="checkbox"/> (B) The Confidential Statement of Formula (CSF) (EPA Form 8750-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF		
(4) The following active ingredients in this product qualify for the formulator's exemption		
Source		
Active Ingredient	Product Name	Registration Number
Imidacloprid [REDACTED]	[REDACTED]	[REDACTED]
Signature 	Name and Title Kelly R. Hoskins, Manager of Regulatory Affairs	Date December 30, 2015

EPA Form 8570-27 (Rev. 8-95)

White - EPA copy
Yellow - Applicant copy

Kumar, Rita

From: Kumar, Rita
Sent: Thursday, December 31, 2015 12:40 PM
To: 'James Messina'
Cc: Benbow, Gene; Carrie Daniels; Lewis, Marianne; Eagle, Venus
Subject: RE: 2517-RTU and 2517-RTG

Importance: High

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Regards,
Rita

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Cc: Benbow, Gene <Benbow.Gene@epa.gov>; Carrie Daniels <cdaniels@exponent.com>
Subject: FW: 2517-RTU and 2517-RTG

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James Messina
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Gene Benbow
Biologist, EPA
Invertebrate & Vertebrate Branch 3
Registration Division
<http://epa.gov/pesticides/>
703-347-0235

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Sent: Tuesday, December 29, 2015 11:55 AM
To: Benbow, Gene <Benbow.Gene@epa.gov>
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Subject: RE: 2517-RTU and 2517-RTG

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1. 91300-2: page 1, 3, 5, 7 *Deg*
2. 91300-3: page 1, 3, 6 *Cole*

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Do not double-dose animals

This comment has already been addressed on the labels. The attached labels include the following statements (under restrictions):

- Use entire contents of tube[vial][applicator][pipette] on each cat. Do not split one tube[vial][applicator][pipette] between two cats. Do not use multiple tube[vial][applicator][pipette]s on one cat.
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This language has been previously approved by EPA on other pet spot-on product labels and it addresses this language requirement.

Other EPA noted label comments

Please note, we have agreed to several label language changes on the attached labels; however, we note that EPA recently approved the same label language it required Sergeant's to change on the December 17, 2015 EPA approvals for 91300-2 and 91300-3. At this time, we request that EPA allow Sergeant's to have the same label claims as EPA approved for the products 91300-2 and 91300-3 noted below:

- No upper weight limit (addressed above)
- "Kills fleas (Ctenocephalides sp.) on your dog and in its environment" (Sergeant's was asked to remove this label claim)
- "Kills fleas on dogs within 12 hours to prevent infestations for [4 weeks][1 month]" (Sergeant's was required to add "further" to this statement and Promika was allowed to not state "further" in the claim)
- "Flea protection" (Sergeant's was required to delete the identical claim)

The only difference between these products is that the 91300 products contain the insect growth regulator (IGR) pyriproxyfen. This IGR does not have any effect on the noted label claims above. We request that EPA allow the same label claims on the Sergeant's labels. This will require us to send you updated labels to review.

I am out of the office this week but I can be reached at 301-908-1181 to discuss any of the information contained in this email or enclosures. I look forward to finalizing these labels with you.

Best Regards,

James Messina
Center Director and Principal Regulatory Consultant
Exponent, Inc.
Center for Chemical Regulation and Food Safety
1150 Connecticut Ave., NW, Suite 1100
Washington, DC 20036
O: 202.772.4932
M: 301.908.1181
jmessina@exponent.com

From: Benbow, Gene [<mailto:Benbow.Gene@epa.gov>]
Sent: Tuesday, December 29, 2015 7:35 AM
To: James Messina
Subject: 2517-RTU and 2517-RTG

Hi Jim,

Rita is away from the office on use-or-lose leave (I think) so Venus is having me work these two product labels up in here absence. I have all the background (list of comments Rita sent you dated 12/4/15, etc.) and just need both labels from you in pdf format if possible. I can then do a final review and hopefully get these moving pretty quickly.

Venus mentioned that you guys were going to do a cite-all for the generic data on a revised matrix for companion animal use. Please send this to me as well if you would, by email if you prefer.

For label comments on 2517-RTG, the only one I see that appears to not have been captured in this email to you from Rita on 12/13/15 is the upper weight limit for the larger package (8 oz). The "do not double-dose animals...." text she was asking for if that rings a bell. I haven't reviewed -RTU yet.

Thanks,

Gene Benbow

Biologist, EPA

Invertebrate & Vertebrate Branch 3

Registration Division

<http://epa.gov/pesticides/>

703-347-0235

Kumar, Rita

From: Kumar, Rita
Sent: Sunday, December 13, 2015 9:11 PM
To: 'James Messina'
Cc: Eagle, Venus; Carrie Daniels; Kelly Hoskins (Kelly.Hoskins@perrigo.com)
Subject: RE: 2517-RTG

Dear Jim: As indicated to you last week, all comments listed in the attachment to Agency's pre-decisional letter dated 12/4/2015 have not been resolved. Please see below for details on the cat product. Refer to the 12/4/2015 attachment for comment numbers:

1. Resolved.
2. Resolved.
3. Not resolved. The options for referral statement list insert. You must provide a referral statement if Directions for Use are in the insert.
4. Okay.
5. Not resolved. "same" is not acceptable, as indicated to you previously.
6. Not resolved. The asterisks and repeated listing of Bayer'sr products is too confusing. Write out what you want to convey, and delete redundant text.
7. Okay.
8. Delete the following "Fleas" marketing claims:
 - Kills fleas; Flea protection. These claims are overly broad and general
9. Delete the following "Other" marketing claims:
 - *All claims relating to xx number of applications to xx weeks supply (these do not match the once a month application direction):*
Delete the first X applications X weeks supply line. It is overly broad. The rest must specify 1 tube equals 1 dose 4 weeks supply 1 month supply, 2 tubes equal 2 doses 8 weeks supply etc.
 - *The only flea protection you need for your cat[s] (or qualify this by adding "...when applied monthly [every 30 days]*
In the revised statement, delete the first "]".
10. Resolved.
11. Partially resolved. The last restriction on page 5, "Do not have contact or allow children to have contact with treated area until completely dry" must be bulleted. Additionally, on page 9, optional package copy must list all the restrictions, or add a referral statement for the full list of restrictions.
12. Partially resolved. See #11 above.
13. Not resolved. Delete the graphics that we objected to. Additionally, the two graphics about the product being applied in a line is contrary to the directions under How to Apply on page 6.
14. Resolved.
15. Okay.
16. Okay.
17. Okay.
18. Okay.
19. Okay
20. Okay.
21. Not resolved. Delete the icon Satisfaction Guaranteed, or qualify it with "or your money back".
22. Not resolved. Delete the icon Made in the USA. An alternate source may be made in Europe.
23. Per the implementation of label changes to pet spot on products in 2011:
 - a. The Front Panel is to have a large clear picture of a cat in the weight range for the product as packaged;

b. Provide an upper weight limit for larger cats on front panel of larger size package (8 oz.). Also, for larger size cats, add the restriction: "Do not double- dose animals larger than upper weight limit on the package."

Additional comments: On your last label dated 12/10/2015, As indicated to you earlier, The How to Apply directions on page 8 of 11 are inconsistent with page 10 optional package copy or insert. Make these consistent. We prefer the number and bullet format for How to apply, it is much clearer for the user.

Regards,
Rita

From: James Messina [mailto:jmessina@exponent.com]
Sent: Thursday, December 10, 2015 9:32 AM
To: Kumar, Rita <Kumar.Rita@epa.gov>
Cc: Eagle, Venus <Eagle.Venus@epa.gov>; Carrie Daniels <cdaniels@exponent.com>; Kelly Hoskins (Kelly.Hoskins@perrigo.com) <Kelly.Hoskins@perrigo.com>
Subject: 2517-RTG

Dear Rita,

Thank you again for reviewing the label comment response for 2517-RTG so quickly. Please find attached an updated label (track changes and clean versions).

The following provides feedback on the few outstanding issues related to EPA's additional comments below:

3. Your response is partially acceptable. You may indicate full precautionary statements on the side or back panels. However, the human hazard statements must be indicated on the package itself. And the First Aid box must be placed above the Precautionary Statements. Additionally, the signal word "Warning" must be placed at the beginning of the paragraph, before "Hazards to Humans", and it must be in a larger size font for prominence.

Sergeant's Response: We have reviewed the label regulations at 40 CFR 156.10 and the LRM and do not see the requirement to place the first aid box above the precautionary statements. Further, we have checked several EPA stamped approved labels (11556-116 and others) and there appears to be no consistency with location of first aid above the precautionary statements. During our review we have noted that many products have the first aid on the inside panel or on the insert inside of the box. We believe this is due to the fact that there are numerous label language requirements to be placed on a limited space label/package. Please note we are not proposing this for our label, but merely pointing it out to EPA. Based upon our research, we have left the location as is on the updated label. We checked the updated label and the signal word (warning) follows the heading Hazards to Humans and is before the actual text. This is consistent with the LRM and several EPA stamped approved labels (11556-116, 2596-183 and others). We have left the location as is on the updated label.

5. Your response is not acceptable. You must delete the optional word "[same]" from: "Contains imidacloprid, the same active ingredient used in....." or any similar statements. This implies comparison, which is not allowed.

Sergeant's Response: We have complied with EPA requirements to delete any comparative language; however, we believe the use of the word "same" is factually correct. The active ingredient in this product is imidacloprid. It is sourced from EPA registered technical grade active ingredients (TGAI's) consisting of imidacloprid. By registering these TGAI's, EPA has determined that they all contain imidacloprid. Further, it is our understanding that all imidacloprid containing TGAI's have cited the same Bayer database. Therefore, Sergeant's

product does contain the “same” active ingredient as the other registered imidacloprid containing end-use products. Again, we believe this is factually correct. We request that EPA allow us to maintain the word “same” on the product label.

7. Your response is acceptable, although this makes the label very confusing. The important text like precautionary statements and directions for use are not as clear and prominent as they should be.

Sergeant’s Response: It is our preference to maintain the optional marketing language in the current location on the updated label. Please note, that Sergeant’s will comply with the EPA labeling requirements on its FPL so that the required language is clear and prominent.

8. Your response is partially acceptable. Study in the cited MRID(44256902) does not support inclusion of this claim. As we wrote to you before, Bayer has been contacted regarding this issue. This claim of controlling fleas in cat’s surroundings” or cat’s environment”) is not acceptable, and must be deleted.

Sergeant’s Response: It is our understanding that BAH is being required to remove this statement from its label. In good faith, Sergeant’s has agreed to remove it from the updated label.

9. Your response is partially acceptable. Please see below:

a. Bullet regarding: xx number of applications to xx weeks supply will be more clear if you changed “applications” to a descriptor term for the applicator (tube, vial, pipette etc.).

Sergeant’s Response: Updated label

b. Bullet # 1: The word specially indicates this formulation is unique for dogs, which is not true. Therefore “specially” must be deleted.

Sergeant’s Response: We have deleted “Specially” on the label.

c. Bullet regarding: “Best if applied year round” is not acceptable, there are no fleas in winter in many parts of the country.

Sergeant’s Response: We do not understand why the Agency has a concern about recommending that the end-user use this product every month of the year. While the label recommends a monthly use, it makes better sense to inform the end-user that using it for the full year will provide continued monthly protection. EPA notes that in many parts of the country fleas might not be present in winter. Please note this is a nationally registered product label. In the USA Fleas are a year around problem. VetMd websites states the following:

“For those of us with pets, we look forward to winter as a time of respite from the bugs that torment us and our pets. We look forward to a break from the sprays and gels and powders and medicines ... all the things we try on our pets and in our home to keep the blood suckers at bay. However -- and we hope you are sitting down as you read this -- winter does not necessarily spell the end of bug season. Consider the following ...

A New Housemate: Fleas and Ticks

The flea is a very persistent and resilient pest with a very complicated life cycle. It is even capable of surviving in outdoor temperatures as low as the upper 30s. As long as an adult flea can find a suitable host to feed from (such as wild animals or your pet), it can stay warm and healthy through the cold season. Their pupae remain settled in their cocoons until it is warm enough to come out -- as long as they have been placed in a location where they are protected from freezing cold (for example, a garage, covered patio, or basement).

Flea pupae can remain dormant for over a year until the surroundings have reached ideal temperatures. Once conditions are ideal (either inside or outside), the pupae will complete their

development and emerge from their cocoons en masse, resulting in a surge of activity both on and off your pets.

Generally speaking, 65-80 degrees Fahrenheit with 75-85 percent humidity is the ideal temperature range for growth and reproduction of fleas. All they need is a warm place in which to settle and lay their eggs. For the majority of pet owners who keep their homes at a consistently warm temperature throughout the winter season, this can mean that a flea population, once settled indoors, can remain active all year long.

For residents of the southern states of the U.S., where the winter season may only go as low as the 30s, fleas will often stay active throughout most or all of the winter season. Only sustained cold (less than 30 degrees) and low humidity levels will kill off outdoor eggs, larvae, and adult fleas.

The best time to fight fleas is during the winter, when there is the best chance that they will become less active and fewer in number. Regularly vacuuming the areas where your pet spends time and continuing regular flea treatments throughout the winter season are the best ways to combat them before the next flea season is in full swing.”

http://www.petmd.com/dog/seasonal/evr_multi_flea_tick_mosquito_care_during_winter

Based upon the above information, we request to keep this statement on the label.

10. See #5 above.

Sergeant’s Response: Please refer to response to #5 above.

18. Your response is acceptable, but we have been asking all registrants to place Storage and Disposal statements inside a solid line box, and suggest that you follow the same format for consistency.

Sergeant’s Response: At this time, Sergeant’s chooses not to include a solid line box. It will ensure that the Storage and Disposal directions are clear and understandable.

21. Graphic with the text: Satisfaction Guaranteed is not acceptable. This must be qualified with “or your money back”.

Sergeant’s Response: Sergeant’s label includes a Good Housekeeping icon and a Satisfaction Guaranteed icon. These icons do not have any FIFRA implications nor are they regulated under FIFRA. The EPA Label Review Manual states the following

“The following graphics and symbols are considered acceptable and may be ignored during, and are not part of, the label review. 1. The “Good Housekeeping Seal of Approval” is a limited warranty to consumers and promises to refund the purchase price or replace the product if defective. While the Agency allows this symbol to be placed on products, the agency does not endorse the warranty message provided by this symbol.”

Further, the Satisfaction Guaranteed icon is a general statement notifying the end-user that their use of this product will be backed by the seller to ensure their satisfaction with the product. This is part of Sergeant’s product stewardship program. The manner in which Sergeant’s responds to a customer related to possible dissatisfaction with the purchase and/or use of the product is at Sergeant’s discretion.

We have also reviewed the LRM (Chapter 12) and do not see any EPA requirements that do not allow the statement/graphic “Satisfaction Guaranteed”. The LRM discusses the following types of statements that should be assessed on a case-by-case basis: 1. Over broad statements negating

or detracting from the Directions for Use or other label language... 2. Label language asserting that the buyer has accepted the manufacturer's statement of his/her respective rights... 3. Overly broad language implying buyer has no legal right to recover damages from manufacturer... The proposed statement is not false and/or misleading, nor does it negate or detract from Directions for Use, nor does it waive any respective rights. In fact, the proposed statement is just the opposite in that it guarantees the satisfaction of the user/purchaser. Sergeant's requests to keep this statement on the label.

22. Graphic with the text: Made in the USA is acceptable. This is not a true statement for all alternate formulations, and is misleading.

Sergeant's Response: The attached label includes two icons related to Made in the USA:

- Made in the USA
- Made in the USA With Global Materials

Both icons do not have any FIFRA implications nor are they regulated under FIFRA. These statements are regulated and enforced by the Federal Trade Commission (FTC). Sergeant's FPL will be in compliance with the FTC with regards to the U.S. Origin Claims by using the appropriate icon based upon the source of product ingredients; therefore, it will not be misleading. Sergeant's requests to keep this language and graphics on the label.

In addition we have noted the following on the revised label that you submitted:

1. On page 1, for different size dogs, the package size must be mentioned (like 0.4 ml, 1.0 ml, 2.5 ml, 4.0 ml), to associate with corresponding size and weight of dog. An example is: For use ONLY on dogs weighing 3.5 to 10 lbs and over 7 weeks (0.4 ml size package). **[Updated on label to reflect as informational text for the reviewer]**

2. The cat icon on page 7 needs to be bigger, and moved to the right side of page. **[Not applicable for the cat product label]**

3. The How to Apply instructions on page 8 are confusing. For clarity and consistency, replace these with step by step and bulleted instructions on page

Sergeant's Response: The Directions for Use found on this product label are identical in format to all EPA approved spot-on products under Sergeant's. The language has been used for 15+ years without any issues with EPA or confusion in the marketplace. Sergeant's has not received any consumer complaints about the Directions for Use.

The text under How to Apply is a summary of the detailed Directions for Use. This language is presented in a paragraph format and a numbered format. Again this language is on all of Sergeant's EPA approved spot-on products. We have not had any issues or comments from EPA with regards to this text.

The language in question is found on all Sergeant's spot-on EPA approved labels. For consistency purposes and to avoid any confusion in the marketplace, we are unable to revise this text.

4. On page 10, Under How to Apply, you are referring to a label icon. Explain what label icon this is, or provide the graphic here. **[Updated on label to include a reference statement to optional graphics found on last page of label]**

5. On page 12, explain what label code are you referring to. **[Updated on label. Note this is an internal Sergeant's product number for tracking purposes. It is unique to the product.]**

6. On page 8, the Do Not statements must be moved under Restrictions on page 6.

Sergeant's Response: The label language found on page 8 is optional product stewardship language that Sergeant's initiated and developed, providing it to EPA in 2009. This language is standard and is found on all of Sergeant's pet spot-on EPA approved product labels. These statements were not required by EPA as restrictions based upon a safety concern, rather they are part of additional registrant lead protective language. It is not possible to change it as it could create confusion in the marketplace because of other marketing materials that stores use reflecting the same language.

7. Graphic and text related to flea larvae. This claim is not supported. **[Updated on label]**

EPA noted the following comment on the 2517-RTU label comments: There is one optional statement on page 9: "Do not reapply for four [4] weeks [30 days]." This statement is not optional, and it must be moved to Restrictions on page 6.

Sergeant's Response: We have not moved this statement on this label. We have left it under Frequency of Application. The BAH stamped approved label (11556-116) states "In case of severe flea infestation, retreatment may be necessary earlier than four weeks. Do not retreat more often than once every seven days. After flea control is attained, return to a monthly retreatment schedule." Based upon this EPA approved label language we believe it would be misleading to list this as a restriction on our label.

Please review the attached updated product label for 2517-RTG and let me know if the EPA has additional comments.

Thank you again for your hard work on this label and turning it around so quickly. We look forward to working with you to try to finalize it.

Please contact me with any questions.

Best Regards,

James Messina

Center Director and Principal Regulatory Consultant

Exponent[®], Inc | Center for Chemical Regulation and Food Safety

1150 Connecticut Ave., NW, Suite 1100

Washington, DC, United States of America

p: 202-772-4932 | c: 301-908-1181 | f: 202-772-4979

e: jmessina@exponent.com | web: www.exponent.com

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Kumar, Rita

From: James Messina <jmessina@exponent.com>
Sent: Thursday, December 10, 2015 5:31 PM
To: Eagle, Venus; Kumar, Rita
Cc: Kelly Hoskins (Kelly.Hoskins@perrigo.com); Carrie Daniels
Subject: 2517-RTU and 2517-RTG

Dear Venus and Rita,

On behalf of my client, Sergeant's Pet Care Products, Inc., we are requesting that EPA move into the additional 30-day timeframe in compliance with EPA's Predecisional letter for 2517-RTU and 2517-RTG to allow us to work with EPA to resolve the remaining label comments. We understand that EPA will have addressed its PRIA requirements with regard to the due date and that the additional 30 days will be used to resolve the remaining label issues and for EPA to issue the EPA stamped approved labels.

We have received EPA's label comments and will work to submit revised labels early next week in hopes that they will be acceptable to EPA.

Please let me know if you have any questions or need any additional information. It is our clients intent to resolve the label issues and obtain the EPA approvals in as timely manner as possible.

Best Regards,

James Messina
Center Director and Principal Regulatory Consultant
Exponent[®], Inc | Center for Chemical Regulation and Food Safety
1150 Connecticut Ave., NW, Suite 1100
Washington, DC, United States of America
p: 202-772-4932 | c: 301-908-1181 | f: 202-772-4979
e: jmessina@exponent.com | web: www.exponent.com

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Kumar, Rita

From: James Messina <jmessina@exponent.com>
Sent: Tuesday, December 15, 2015 4:33 PM
To: Kumar, Rita
Cc: Eagle, Venus; Carrie Daniels; Kelly Hoskins (Kelly.Hoskins@perrigo.com)
Subject: RE: 2517-RTG
Attachments: 2517-RTG Revised Label 12-15-15 track.docx

Dear Rita and Venus,

Thank you for sending your additional comments on the draft label. As discussed with Venus on December 10, 2015, we have updated the label (attached). Please see below in red for how we addressed those marked as "Not resolved". We request that you do not start to review this label as we would like to have a call to discuss the following comments:

6. Not resolved. The asterisks and repeated listing of Bayer's products is too confusing. Write out what you want to convey, and delete redundant text.

Sergeant's Response: We would like to discuss the example statement we provided. We have listed the referral to comply with EPA guidance and the requirement to reflect the appropriate ABN's for the basic registrations.

8. Delete the following "Fleas" marketing claims:

- Kills fleas; Flea protection. These claims are overly broad and general

Sergeant's Response: We deleted "Flea protection". (We want to discuss "Kills fleas.") *okay*

9. Delete the following "Other" marketing claims:

- All claims relating to xx number of applications to xx weeks supply (these do not match the once a month application direction):

Sergeant's Response: We would like to discuss this section as our client wants to have the various options available to compete with other registrants. The statements might be used together or individually based upon the number of tubes in the package.

11. Partially resolved. The last restriction on page 5, "Do not have contact or allow children to have contact with treated area until completely dry" must be bulleted. Additionally, on page 9, optional package copy must list all the restrictions, or add a referral statement for the full list of restrictions.

Sergeant's Response: We bulleted the first statement above. We do not agree to update the text on page 9 or provide a referral statement to the EPA requested restrictions. We also want to discuss the comparison of the BAH label restrictions versus Sergeant's. BAH is only required to have the following on its labels:

- Use only on cats 8 weeks and older. Do not use on other animals. Do not apply to kittens or cats weighing less than 2 lbs.
- Do not apply more than one (1) tube per treatment.
- Do not have contact or allow children to have contact with the treated area until completely dry.

EPA has asked Sergeant's to have the following on its me-too label:

- **DO NOT ALLOW CHILDREN TO APPLY PRODUCT.**
- Do not use on animals other than cats.
- Do not allow your cat to ingest this product.
- Do not reapply for [[four][4] weeks][30 days].

- Do not use on kittens under 8 weeks of age. Do not apply to cats weighing less than 2[9] lbs.
- Use entire contents of tube[vial][applicator][pipette] on each cat. Do not split one tube[vial][applicator][pipette] between two cats. Do not use multiple tube[vial][applicator][pipette]s on one cat.
- Weigh your cat to be sure you are applying the right dose formulated for the weight of your cat.
- Separate the treated cat from all other cats and dogs for 24 hours after treatment has been applied.
- Do not have contact or allow children to have contact with the treated area until completely dry.

These products are based upon the same data. If a customer were to compare the two labels they are naturally going to think that Sergeant's product is different (including more toxic because it has more restrictions). Much of the text found on Sergeant's label was proposed by Sergeant's as good product stewards and is not required by EPA. We would like to discuss this in more detail.

b. Provide an upper weight limit for larger cats on front panel of larger size package (8 oz.). Also, for larger size cats, add the restriction: "Do not double- dose animals larger than upper weight limit on the package.

Sergeant's Response: This is not required per the pet spot-on mitigation letter, nor is it found on the BAH labels (11556-116 or 11556-118). Further, we reviewed many of the EPA approved pet spot-on labels for large dose and did not find it on other labels. This would put Sergeant's at an extreme disadvantage in the marketplace. Further by requiring it on Sergeant's and BAH's label, it would put both companies at an extreme disadvantage in the marketplace. We would like to discuss this in more detail.

Please let me know if you are available this afternoon or tomorrow morning for a call. The intent is to clarify the above, then incorporate any label changes and email that version to you for review and approval. We would like to try to obtain the EPA stamped approved label before the holidays if possible.

Best Regards,

James Messina
Center Director and Principal Regulatory Consultant
Exponent, Inc.
Center for Chemical Regulation and Food Safety
1150 Connecticut Ave., NW, Suite 1100
Washington, DC 20036
O: 202.772.4932
M: 301.908.1181
jmessina@exponent.com

From: Kumar, Rita [<mailto:Kumar.Rita@epa.gov>]
Sent: Sunday, December 13, 2015 9:11 PM
To: James Messina
Cc: Eagle, Venus; Carrie Daniels; Kelly Hoskins (Kelly.Hoskins@perrigo.com)
Subject: RE: 2517-RTG

Dear Jim: As indicated to you last week, all comments listed in the attachment to Agency's pre-decisional letter dated 12/4/2015 have not been resolved. Please see below for details on the cat product. Refer to the 12/4/2015 attachment for comment numbers:

1. Resolved.
2. Resolved.
3. Not resolved. The options for referral statement list insert. You must provide a referral statement if Directions for Use are in the insert. We deleted the option for an "insert".
4. Okay.

5. Not resolved. "same" is not acceptable, as indicated to you previously. We deleted "same".
6. Not resolved. The asterisks and repeated listing of Bayer'sr products is too confusing. Write out what you want to convey, and delete redundant text. To be discussed.
7. Okay.
8. Delete the following "Fleas" marketing claims:
 - Kills fleas; Flea protection. These claims are overly broad and general Discuss kills fleas. We deleted Flea Protection.
9. Delete the following "Other" marketing claims:
 - *All claims relating to xx number of applications to xx weeks supply (these do not match the once a month application direction):*
Delete the first X applications X weeks supply line. It is overly broad. The rest must specify 1 tube equals 1 dose 4 weeks supply 1 month supply, 2 tubes equal 2 doses 8 weeks supply etc. To be discussed.
 - *The only flea protection you need for your cat[s] (or qualify this by adding "...when applied monthly [every 30 days]*
In the revised statement, delete the first "]". Updated on the label.
10. Resolved.
11. Partially resolved. The last restriction on page 5, "Do not have contact or allow children to have contact with treated area until completely dry" must be bulleted. Additionally, on page 9, optional package copy must list all the restrictions, or add a referral statement for the full list of restrictions. We bulleted the first part but want to discuss the second request.
12. Partially resolved. See #11 above. To be discussed.
13. Not resolved. Delete the graphics that we objected to. Additionally, the two graphics about the product being applied in a line is contrary to the directions under How to Apply on page 6. Updated on label.
14. Resolved.
15. Okay.
16. Okay.
17. Okay.
18. Okay.
19. Okay
20. Okay.
21. Not resolved. Delete the icon Satisfaction Guaranteed, or qualify it with "or your money back". We proposed a footnote to the graphic to allow it to remain on the label. We would like to discuss it with EPA. We want to note that this is not a FIFRA regulated label statement or requirement.
22. Not resolved. Delete the icon Made in the USA. An alternate source may be made in Europe. Updated on the label. We want to note that this is not a FIFRA regulated label statement or requirement. We plan to address this via a label amendment after registration.
23. Per the implementation of label changes to pet spot on products in 2011:
 - a. The Front Panel is to have a large clear picture of a cat in the weight range for the product as packaged; Updated on the label to include a reviewer note.
 - b. Provide an upper weight limit for larger cats on front panel of larger size package (8 oz.). Also, for larger size cats, add the restriction: "Do not double- dose animals larger than upper weight limit on the package." To be discussed.

Additional comments: On your last label dated 12/10/2015, As indicated to you earlier, The How to Apply directions on page 8 of 11 are inconsistent with page 10 optional package copy or insert. Make these consistent. We prefer the number and bullet format for How to apply, it is much clearer for the user. The language found on both pages of the label is identical except for the number format in the one version. We have updated the label to reflect the numbered version but will address this in a label amendment after registration.

Regards,
Rita

From: James Messina [mailto:jmessina@exponent.com]

Sent: Thursday, December 10, 2015 9:32 AM

To: Kumar, Rita <Kumar.Rita@epa.gov>

Cc: Eagle, Venus <Eagle.Venus@epa.gov>; Carrie Daniels <cdaniels@exponent.com>; Kelly Hoskins (Kelly.Hoskins@perrigo.com) <Kelly.Hoskins@perrigo.com>

Subject: 2517-RTG

Dear Rita,

Thank you again for reviewing the label comment response for 2517-RTG so quickly. Please find attached an updated label (track changes and clean versions).

The following provides feedback on the few outstanding issues related to EPA's additional comments below:

3. Your response is partially acceptable. You may indicate full precautionary statements on the side or back panels. However, the human hazard statements must be indicated on the package itself. And the First Aid box must be placed above the Precautionary Statements. Additionally, the signal word "Warning" must be placed at the beginning of the paragraph, before "Hazards to Humans", and it must be in a larger size font for prominence.

Sergeant's Response: We have reviewed the label regulations at 40 CFR 156.10 and the LRM and do not see the requirement to place the first aid box above the precautionary statements. Further, we have checked several EPA stamped approved labels (11556-116 and others) and there appears to be no consistency with location of first aid above the precautionary statements. During our review we have noted that many products have the first aid on the inside panel or on the insert inside of the box. We believe this is due to the fact that there are numerous label language requirements to be placed on a limited space label/package. Please note we are not proposing this for our label, but merely pointing it out to EPA. Based upon our research, we have left the location as is on the updated label. We checked the updated label and the signal word (warning) follows the heading Hazards to Humans and is before the actual text. This is consistent with the LRM and several EPA stamped approved labels (11556-116, 2596-183 and others). We have left the location as is on the updated label.

5. Your response is not acceptable. You must delete the optional word "[same]" from: "Contains imidacloprid, the same active ingredient used in....." or any similar statements. This implies comparison, which is not allowed.

Sergeant's Response: We have complied with EPA requirements to delete any comparative language; however, we believe the use of the word "same" is factually correct. The active ingredient in this product is imidacloprid. It is sourced from EPA registered technical grade active ingredients (TGAI's) consisting of imidacloprid. By registering these TGAI's, EPA has determined that they all contain imidacloprid. Further, it is our understanding that all imidacloprid containing TGAI's have cited the same Bayer database. Therefore, Sergeant's product does contain the "same" active ingredient as the other registered imidacloprid containing end-use products. Again, we believe this is factually correct. We request that EPA allow us to maintain the word "same" on the product label.

7. Your response is acceptable, although this makes the label very confusing. The important text like precautionary statements and directions for use are not as clear and prominent as they should be.

Sergeant's Response: It is our preference to maintain the optional marketing language in the current location on the updated label. Please note, that Sergeant's will comply with the EPA labeling requirements on its FPL so that the required language is clear and prominent.

8. Your response is partially acceptable. Study in the cited MRID(44256902) does not support inclusion of this claim. As we wrote to you before, Bayer has been contacted regarding this issue. This claim of controlling fleas in cat's surroundings" or cat's environment") is not acceptable, and must be deleted.

Sergeant's Response: It is our understanding that BAH is being required to remove this statement from its label. In good faith, Sergeant's has agreed to remove it from the updated label.

9. Your response is partially acceptable. Please see below:

a. Bullet regarding: xx number of applications to xx weeks supply will be more clear if you changed "applications" to a descriptor term for the applicator (tube, vial, pipette etc.).

Sergeant's Response: Updated label

b. Bullet # 1: The word specially indicates this formulation is unique for dogs, which is not true. Therefore "specially" must be deleted.

Sergeant's Response: We have deleted "Specially" on the label.

c. Bullet regarding: "Best if applied year round" is not acceptable, there are no fleas in winter in many parts of the country.

Sergeant's Response: We do not understand why the Agency has a concern about recommending that the end-user use this product every month of the year. While the label recommends a monthly use, it makes better sense to inform the end-user that using it for the full year will provide continued monthly protection. EPA notes that in many parts of the country fleas might not be present in winter. Please note this is a nationally registered product label. In the USA Fleas are a year around problem. VetMdl websites states the following:

"For those of us with pets, we look forward to winter as a time of respite from the bugs that torment us and our pets. We look forward to a break from the sprays and gels and powders and medicines ... all the things we try on our pets and in our home to keep the blood suckers at bay. However -- and we hope you are sitting down as you read this -- winter does not necessarily spell the end of bug season. Consider the following ...

A New Housemate: Fleas and Ticks

The flea is a very persistent and resilient pest with a very complicated life cycle. It is even capable of surviving in outdoor temperatures as low as the upper 30s. As long as an adult flea can find a suitable host to feed from (such as wild animals or your pet), it can stay warm and healthy through the cold season. Their pupae remain settled in their cocoons until it is warm enough to come out -- as long as they have been placed in a location where they are protected from freezing cold (for example, a garage, covered patio, or basement).

Flea pupae can remain dormant for over a year until the surroundings have reached ideal temperatures. Once conditions are ideal (either inside or outside), the pupae will complete their development and emerge from their cocoons en masse, resulting in a surge of activity both on and off your pets.

Generally speaking, 65-80 degrees Fahrenheit with 75-85 percent humidity is the ideal temperature range for growth and reproduction of fleas. All they need is a warm place in which to settle and lay their eggs. For the majority of pet owners who keep their homes at a consistently warm temperature throughout the winter season, this can mean that a flea population, once settled indoors, can remain active all year long.

For residents of the southern states of the U.S., where the winter season may only go as low as the 30s, fleas will often stay active throughout most or all of the winter season. Only sustained cold (less than 30 degrees) and low humidity levels will kill off outdoor eggs, larvae, and adult fleas.

The best time to fight fleas is during the winter, when there is the best chance that they will become less active and fewer in number. Regularly vacuuming the areas where your pet spends time and continuing regular flea treatments throughout the winter season are the best ways to combat them before the next flea season is in full swing.”

http://www.petmd.com/dog/seasonal/evr_multi_flea_tick_mosquito_care_during_winter

Based upon the above information, we request to keep this statement on the label.

10. See #5 above.

Sergeant’s Response: Please refer to response to #5 above.

18. Your response is acceptable, but we have been asking all registrants to place Storage and Disposal statements inside a solid line box, and suggest that you follow the same format for consistency.

Sergeant’s Response: At this time, Sergeant’s chooses not to include a solid line box. It will ensure that the Storage and Disposal directions are clear and understandable.

21. Graphic with the text: Satisfaction Guaranteed is not acceptable. This must be qualified with “or your money back”.

Sergeant’s Response: Sergeant’s label includes a Good Housekeeping icon and a Satisfaction Guaranteed icon. These icons do not have any FIFRA implications nor are they regulated under FIFRA. The EPA Label Review Manual states the following

“The following graphics and symbols are considered acceptable and may be ignored during, and are not part of, the label review. 1. The “Good Housekeeping Seal of Approval” is a limited warranty to consumers and promises to refund the purchase price or replace the product if defective. While the Agency allows this symbol to be placed on products, the agency does not endorse the warranty message provided by this symbol.”

Further, the Satisfaction Guaranteed icon is a general statement notifying the end-user that their use of this product will be backed by the seller to ensure their satisfaction with the product. This is part of Sergeant’s product stewardship program. The manner in which Sergeant’s responds to a customer related to possible dissatisfaction with the purchase and/or use of the product is at Sergeant’s discretion.

We have also reviewed the LRM (Chapter 12) and do not see any EPA requirements that do not allow the statement/graphic “Satisfaction Guaranteed”. The LRM discusses the following types of statements that should be assessed on a case-by-case basis: 1. Over broad statements negating or detracting from the Directions for Use or other label language... 2. Label language asserting that the buyer has accepted the manufacturer’s statement of his/her respective rights... 3. Overly broad language implying buyer has no legal right to recover damages from manufacturer... The proposed statement is not false and/or misleading, nor does it negate or detract from Directions for Use, nor does it waive any respective rights. In fact, the proposed statement is just the opposite in that it guarantees the satisfaction of the user/purchaser. Sergeant’s requests to keep this statement on the label.

22. Graphic with the text: Made in the USA is acceptable. This is not a true statement for all alternate formulations, and is misleading.

Sergeant's Response: The attached label includes two icons related to Made in the USA:

- **Made in the USA**
- **Made in the USA With Global Materials**

Both icons do not have any FIFRA implications nor are they regulated under FIFRA. These statements are regulated and enforced by the Federal Trade Commission (FTC). Sergeant's FPL will be in compliance with the FTC with regards to the U.S. Origin Claims by using the appropriate icon based upon the source of product ingredients; therefore, it will not be misleading. Sergeant's requests to keep this language and graphics on the label.

In addition we have noted the following on the revised label that you submitted:

1. On page 1, for different size dogs, the package size must be mentioned (like 0.4 ml, 1.0 ml, 2.5 ml, 4.0 ml), to associate with corresponding size and weight of dog. An example is: For use ONLY on dogs weighing 3.5 to 10 lbs and over 7 weeks (0.4 ml size package). **[Updated on label to reflect as informational text for the reviewer]**

2. The cat icon on page 7 needs to be bigger, and moved to the right side of page. **[Not applicable for the cat product label]**

3. The How to Apply instructions on page 8 are confusing. For clarity and consistency, replace these with step by step and bulleted instructions on page

Sergeant's Response: The Directions for Use found on this product label are identical in format to all EPA approved spot-on products under Sergeant's. The language has been used for 15+ years without any issues with EPA or confusion in the marketplace. Sergeant's has not received any consumer complaints about the Directions for Use.

The text under How to Apply is a summary of the detailed Directions for Use. This language is presented in a paragraph format and a numbered format. Again this language is on all of Sergeant's EPA approved spot-on products. We have not had any issues or comments from EPA with regards to this text.

The language in question is found on all Sergeant's spot-on EPA approved labels. For consistency purposes and to avoid any confusion in the marketplace, we are unable to revise this text.

4. On page 10, Under How to Apply, you are referring to a label icon. Explain what label icon this is, or provide the graphic here. **[Updated on label to include a reference statement to optional graphics found on last page of label]**

5. On page 12, explain what label code are you referring to. **[Updated on label. Note this is an internal Sergeant's product number for tracking purposes. It is unique to the product.]**

6. On page 8, the Do Not statements must be moved under Restrictions on page 6.

Sergeant's Response: The label language found on page 8 is optional product stewardship language that Sergeant's initiated and developed, providing it to EPA in 2009. This language is standard and is found on all of Sergeant's pet spot-on EPA approved product labels. These statements were not required by EPA as restrictions based upon a safety concern, rather they are part of additional registrant lead protective language. It is not possible to change it as it could create confusion in the marketplace because of other marketing materials that stores use reflecting the same language.

7. Graphic and text related to flea larvae. This claim is not supported. **[Updated on label]**

EPA noted the following comment on the 2517-RTU label comments: There is one optional statement on page 9: "Do not reapply for four [4] weeks [30 days]." This statement is not optional, and it must be moved to Restrictions on page 6.

Sergeant's Response: We have not moved this statement on this label. We have left it under Frequency of Application. The BAH stamped approved label (11556-116) states "In case of severe flea infestation, retreatment may be necessary earlier than four weeks. Do not retreat more often than once every seven days. After flea control is

attained, return to a monthly retreatment schedule.” Based upon this EPA approved label language we believe it would be misleading to list this as a restriction on our label.

Please review the attached updated product label for 2517-RTG and let me know if the EPA has additional comments.

Thank you again for your hard work on this label and turning it around so quickly. We look forward to working with you to try to finalize it.

Please contact me with any questions.

Best Regards,

James Messina
Center Director and Principal Regulatory Consultant
Exponent[®], Inc | Center for Chemical Regulation and Food Safety
1150 Connecticut Ave., NW, Suite 1100
Washington, DC, United States of America
p: 202-772-4932 | c: 301-908-1181 | f: 202-772-4979
e: jmessina@exponent.com | web: www.exponent.com

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12/10

Eagle, Venus

From: James Messina <jmessina@exponent.com>
Sent: Thursday, December 10, 2015 9:32 AM
To: Kumar, Rita
Cc: Eagle, Venus; Carrie Daniels; Kelly Hoskins (Kelly.Hoskins@perrigo.com)
Subject: 2517-RTG
Attachments: 2517-RTG Revised Label 12-9-15 clean.docx; 2517-RTG Revised Label 12-9-15 track.docx

Dear Rita,

Thank you again for reviewing the label comment response for 2517-RTG so quickly. Please find attached an updated label (track changes and clean versions).

The following provides feedback on the few outstanding issues related to EPA's additional comments below:

3. Your response is partially acceptable. You may indicate full precautionary statements on the side or back panels. However, the human hazard statements must be indicated on the package itself. And the First Aid box must be placed above the Precautionary Statements. Additionally, the signal word "Warning" must be placed at the beginning of the paragraph, before "Hazards to Humans", and it must be in a larger size font for prominence.

Sergeant's Response: We have reviewed the label regulations at 40 CFR 156.10 and the LRM and do not see the requirement to place the first aid box above the precautionary statements. Further, we have checked several EPA stamped approved labels (11556-116 and others) and there appears to be no consistency with location of first aid above the precautionary statements. During our review we have noted that many products have the first aid on the inside panel or on the insert inside of the box. We believe this is due to the fact that there are numerous label language requirements to be placed on a limited space label/package. Please note we are not proposing this for our label, but merely pointing it out to EPA. Based upon our research, we have left the location as is on the updated label. We checked the updated label and the signal word (warning) follows the heading Hazards to Humans and is before the actual text. This is consistent with the LRM and several EPA stamped approved labels (11556-116, 2596-183 and others). We have left the location as is on the updated label.

5. Your response is not acceptable. You must delete the optional word "[same]" from: "Contains imidacloprid, the same active ingredient used in....." or any similar statements. This implies comparison, which is not allowed.

Sergeant's Response: We have complied with EPA requirements to delete any comparative language; however, we believe the use of the word "same" is factually correct. The active ingredient in this product is imidacloprid. It is sourced from EPA registered technical grade active ingredients (TGAI's) consisting of imidacloprid. By registering these TGAI's, EPA has determined that they all contain imidacloprid. Further, it is our understanding that all imidacloprid containing TGAI's have cited the same Bayer database. Therefore, Sergeant's product does contain the "same" active ingredient as the other registered imidacloprid containing end-use products. Again, we believe this is factually correct. We request that EPA allow us to maintain the word "same" on the product label.

7. Your response is acceptable, although this makes the label very confusing. The important text like precautionary statements and directions for use are not as clear and prominent as they should be.

Sergeant's Response: It is our preference to maintain the optional marketing language in the current location on the updated label. Please note, that Sergeant's will comply with the EPA labeling requirements on its FPL so that the required language is clear and prominent.

8. Your response is partially acceptable. Study in the cited MRID(44256902) does not support inclusion of this claim. As we wrote to you before, Bayer has been contacted regarding this issue. This claim of controlling fleas in cat's surroundings" or cat's environment") is not acceptable, and must be deleted.

Sergeant's Response: It is our understanding that BAH is being required to remove this statement from its label. In good faith, Sergeant's has agreed to remove it from the updated label.

9. Your response is partially acceptable. Please see below:

a. Bullet regarding: xx number of applications to xx weeks supply will be more clear if you changed "applications" to a descriptor term for the applicator (tube, vial, pipette etc.).

Sergeant's Response: Updated label

b. Bullet # 1: The word specially indicates this formulation is unique for dogs, which is not true. Therefore "specially" must be deleted.

Sergeant's Response: We have deleted "Specially" on the label.

c. Bullet regarding: "Best if applied year round" is not acceptable, there are no fleas in winter in many parts of the country.

Sergeant's Response: We do not understand why the Agency has a concern about recommending that the end-user use this product every month of the year. While the label recommends a monthly use, it makes better sense to inform the end-user that using it for the full year will provide continued monthly protection. EPA notes that in many parts of the country fleas might not be present in winter. Please note this is a nationally registered product label. In the USA Fleas are a year around problem. VetMd websites states the following:

"For those of us with pets, we look forward to winter as a time of respite from the bugs that torment us and our pets. We look forward to a break from the sprays and gels and powders and medicines ... all the things we try on our pets and in our home to keep the blood suckers at bay. However -- and we hope you are sitting down as you read this -- winter does not necessarily spell the end of bug season. Consider the following ...

A New Housemate: Fleas and Ticks

The flea is a very persistent and resilient pest with a very complicated life cycle. It is even capable of surviving in outdoor temperatures as low as the upper 30s. As long as an adult flea can find a suitable host to feed from (such as wild animals or your pet), it can stay warm and healthy through the cold season. Their pupae remain settled in their cocoons until it is warm enough to come out -- as long as they have been placed in a location where they are protected from freezing cold (for example, a garage, covered patio, or basement).

Flea pupae can remain dormant for over a year until the surroundings have reached ideal temperatures. Once conditions are ideal (either inside or outside), the pupae will complete their development and emerge from their cocoons en masse, resulting in a surge of activity both on and off your pets.

Generally speaking, 65-80 degrees Fahrenheit with 75-85 percent humidity is the ideal temperature range for growth and reproduction of fleas. All they need is a warm place in which to settle and lay their eggs. For the majority of pet owners who keep their homes at a consistently

warm temperature throughout the winter season, this can mean that a flea population, once settled indoors, can remain active all year long.

For residents of the southern states of the U.S., where the winter season may only go as low as the 30s, fleas will often stay active throughout most or all of the winter season. Only sustained cold (less than 30 degrees) and low humidity levels will kill off outdoor eggs, larvae, and adult fleas.

The best time to fight fleas is during the winter, when there is the best chance that they will become less active and fewer in number. Regularly vacuuming the areas where your pet spends time and continuing regular flea treatments throughout the winter season are the best ways to combat them before the next flea season is in full swing.”

http://www.petmd.com/dog/seasonal/evr_multi_flea_tick_mosquito_care_during_winter

Based upon the above information, we request to keep this statement on the label.

10. See #5 above.

Sergeant’s Response: Please refer to response to #5 above.

18. Your response is acceptable, but we have been asking all registrants to place Storage and Disposal statements inside a solid line box, and suggest that you follow the same format for consistency.

Sergeant’s Response: At this time, Sergeant’s chooses not to include a solid line box. It will ensure that the Storage and Disposal directions are clear and understandable.

21. Graphic with the text: Satisfaction Guaranteed is not acceptable. This must be qualified with “or your money back”.

Sergeant’s Response: Sergeant’s label includes a Good Housekeeping icon and a Satisfaction Guaranteed icon. These icons do not have any FIFRA implications nor are they regulated under FIFRA. The EPA Label Review Manual states the following

“The following graphics and symbols are considered acceptable and may be ignored during, and are not part of, the label review. 1. The “Good Housekeeping Seal of Approval” is a limited warranty to consumers and promises to refund the purchase price or replace the product if defective. While the Agency allows this symbol to be placed on products, the agency does not endorse the warranty message provided by this symbol.”

Further, the Satisfaction Guaranteed icon is a general statement notifying the end-user that their use of this product will be backed by the seller to ensure their satisfaction with the product. This is part of Sergeant’s product stewardship program. The manner in which Sergeant’s responds to a customer related to possible dissatisfaction with the purchase and/or use of the product is at Sergeant’s discretion.

We have also reviewed the LRM (Chapter 12) and do not see any EPA requirements that do not allow the statement/graphic “Satisfaction Guaranteed”. The LRM discusses the following types of statements that should be assessed on a case-by-case basis: 1. Over broad statements negating or detracting from the Directions for Use or other label language... 2. Label language asserting that the buyer has accepted the manufacturer’s statement of his/her respective rights... 3. Overly broad language implying buyer has no legal right to recover damages from manufacturer... The proposed statement is not false and/or misleading, nor does it negate or detract from Directions for Use, nor does it waiver any respective rights. In fact, the proposed

statement is just the opposite in that it guarantees the satisfaction of the user/purchaser. Sergeant's requests to keep this statement on the label.

22. Graphic with the text: Made in the USA is acceptable. This is not a true statement for all alternate formulations, and is misleading.

Sergeant's Response: The attached label includes two icons related to Made in the USA:

- **Made in the USA**
- **Made in the USA With Global Materials**

Both icons do not have any FIFRA implications nor are they regulated under FIFRA. These statements are regulated and enforced by the Federal Trade Commission (FTC). Sergeant's FPL will be in compliance with the FTC with regards to the U.S. Origin Claims by using the appropriate icon based upon the source of product ingredients; therefore, it will not be misleading. Sergeant's requests to keep this language and graphics on the label.

In addition we have noted the following on the revised label that you submitted:

1. On page 1, for different size dogs, the package size must be mentioned (like 0.4 ml, 1.0 ml, 2.5 ml, 4.0 ml), to associate with corresponding size and weight of dog. An example is: For use ONLY on dogs weighing 3.5 to 10 lbs and over 7 weeks (0.4 ml size package). **[Updated on label to reflect as informational text for the reviewer]**

2. The cat icon on page 7 needs to be bigger, and moved to the right side of page. **[Not applicable for the cat product label]**

3. The How to Apply instructions on page 8 are confusing. For clarity and consistency, replace these with step by step and bulleted instructions on page

Sergeant's Response: The Directions for Use found on this product label are identical in format to all EPA approved spot-on products under Sergeant's. The language has been used for 15+ years without any issues with EPA or confusion in the marketplace. Sergeant's has not received any consumer complaints about the Directions for Use.

The text under How to Apply is a summary of the detailed Directions for Use. This language is presented in a paragraph format and a numbered format. Again this language is on all of Sergeant's EPA approved spot-on products. We have not had any issues or comments from EPA with regards to this text.

The language in question is found on all Sergeant's spot-on EPA approved labels. For consistency purposes and to avoid any confusion in the marketplace, we are unable to revise this text.

4. On page 10, Under How to Apply, you are referring to a label icon. Explain what label icon this is, or provide the graphic here. **[Updated on label to include a reference statement to optional graphics found on last page of label]**

5. On page 12, explain what label code are you referring to. **[Updated on label. Note this is an internal Sergeant's product number for tracking purposes. It is unique to the product.]**

6. On page 8, the Do Not statements must be moved under Restrictions on page 6.

Sergeant's Response: The label language found on page 8 is optional product stewardship language that Sergeant's initiated and developed, providing it to EPA in 2009. This language is standard and is found on all of Sergeant's pet spot-on EPA approved product labels. These statements were not required by EPA as restrictions based upon a safety concern, rather they are part of additional registrant lead protective language. It is not possible to change it as it could create confusion in the marketplace because of other marketing materials that stores use reflecting the same language.

7. Graphic and text related to flea larvae. This claim is not supported. **[Updated on label]**

EPA noted the following comment on the 2517-RTU label comments: There is one optional statement on page 9: "Do not reapply for four [4] weeks [30 days]." This statement is not optional, and it must be moved to Restrictions on page 6.

Sergeant's Response: We have not moved this statement on this label. We have left it under Frequency of Application. The BAH stamped approved label (11556-116) states "In case of severe flea infestation, retreatment may be necessary earlier than four weeks. Do not retreat more often than once every seven days. After flea control is attained, return to a monthly retreatment schedule." Based upon this EPA approved label language we believe it would be misleading to list this as a restriction on our label.

Please review the attached updated product label for 2517-RTG and let me know if the EPA has additional comments.

Thank you again for your hard work on this label and turning it around so quickly. We look forward to working with you to try to finalize it.

Please contact me with any questions.

Best Regards,

James Messina
Center Director and Principal Regulatory Consultant
Exponent[®], Inc | Center for Chemical Regulation and Food Safety
1150 Connecticut Ave., NW, Suite 1100
Washington, DC, United States of America
p: 202-772-4932 | c: 301-908-1181 | f: 202-772-4979
e: jmessina@exponent.com | web: www.exponent.com

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From: Kumar, Rita
Sent: Wednesday, December 09, 2015 9:26 PM
To: 'James Messina'
Cc: Carrie Daniels; Kelly Hoskins (Kelly.Hoskins@perrigo.com); Eagle, Venus
Subject: RE: 2517-RTG Response

Dear Jim: Thanks you for the revised labels, and comments/justification on the comments included in attachment to the pre-decisional letter. You have not complied with the changes that we asked you to make in our letter dated December 4, 2015. Please see details below, the numbers relate to the label comments attachment that was sent to you with this attachment:

1. Your response is acceptable.
2. Your response is acceptable.
3. Your response is partially acceptable. You may indicate full precautionary statements on the side or back panels. However, the human hazard statements must be indicated on the package itself. And the First Aid box must be placed above the Precautionary Statements. Additionally, the signal word "Warning" must be placed at the beginning of the paragraph, before "Hazards to Humans", and it must be in a larger size font for prominence.
4. Your response is acceptable.
5. Your response is not acceptable. You must delete the optional word "[same]" from: "Contains imidacloprid, the same active ingredient used in....." or any similar statements. This implies comparison, which is not allowed.
6. Your response is acceptable.
7. Your response is acceptable, although this makes the label very confusing. The important text like precautionary statements and directions for use are not as clear and prominent as they should be.
8. Your response is partially acceptable. Study in the cited MRID(44256902) does not support inclusion of this claim. As we wrote to you before, Bayer has been contacted regarding this issue. This claim of controlling fleas in cat's surroundings" or cat's environment") is not acceptable, and must be deleted.
9. Your response is partially acceptable. Please see below:
 - a. Bullet regarding: xx number of applications to xx weeks supply will be more clear if you changed "applications" to a descriptor term for the applicator (tube, vial, pipette etc.).
 - b. Bullet # 1: The word specially indicates this formulation is unique for dogs, which is not true. Therefore "specially" must be deleted.
 - c. Bullet regarding: "Best if applied year round" is not acceptable, there are no fleas in winter in many parts of the country.
10. See #5 above.
11. Your response is acceptable.
12. Your response is acceptable.
13. Your response is acceptable.
14. Your response is acceptable.
15. Your response is acceptable.
16. Your response is acceptable.
17. Your response is acceptable.
18. Your response is acceptable, but we have been asking all registrants to place Storage and Disposal statements inside a solid line box, and suggest that you follow the same format for consistency.
19. Your response is acceptable.
20. Your response is acceptable.
21. Graphic with the text: Satisfaction Guaranteed is not acceptable. This must be qualified with "or your money back".

22. Graphic with the text: Made in the USA is acceptable. This is not a true statement for all alternate formulations, and is misleading.
23. Your response is acceptable.

In addition we have noted the following on the revised label that you submitted:

1. On page 1, for different size dogs, the package size must be mentioned (like 0.4 ml, 1.0 ml, 2.5 ml, 4.0 ml), to associate with corresponding size and weight of dog. An example is: For use ONLY on dogs weighing 3.5 to 10 lbs and over 7 weeks (0.4 ml size package).
2. The cat icon on page 7 needs to be bigger, and moved to the right side of page.
3. The How to Apply instructions on page 8 are confusing. For clarity and consistency, replace these with step by step and bulleted instructions on page 10.
4. On page 10, Under How to Apply, you are referring to a label icon. Explain what label icon this is, or provide the graphic here.
5. On page 12, explain what label code are you referring to.
6. On page 8, the Do Not statements must be moved under Restrictions on page 6.
7. Graphic and text related to flea larvae. This claim is not supported.

Please submit revised labeling ASAP.

Thanks,
Rita

From: James Messina [mailto:jmessina@exponent.com]

Sent: Tuesday, December 08, 2015 11:39 AM

To: Kumar, Rita <Kumar.Rita@epa.gov>; Eagle, Venus <Eagle.Venus@epa.gov>

Cc: Carrie Daniels <cdaniels@exponent.com>; Kelly Hoskins (Kelly.Hoskins@perrigo.com) <Kelly.Hoskins@perrigo.com>

Subject: 2517-RTG Response

Dear Rita and Venus,

Please find attached Sergeant's response for 2517-RTG. It is our understanding that EPA will process the email submission. Please let me know if EPA requires a copy to be submitted to document processing.

Please let me know if you have any questions or need any additional information. I will be out of the office at an EPA meeting this afternoon but should be available after 3:00 pm. In my absence, please contact Carrie Daniels at 202-772-4916. Thank you in advance for your time and efforts.

Best Regards,

James Messina

Center Director and Principal Regulatory Consultant

Exponent[®], Inc | Center for Chemical Regulation and Food Safety

1150 Connecticut Ave., NW, Suite 1100

Washington, DC, United States of America

p: 202-772-4932 | c: 301-908-1181 | f: 202-772-4979

e: jmessina@exponent.com | web: www.exponent.com

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Kumar, Rita

Resubmission:

From: James Messina <jmessina@exponent.com>
Sent: Tuesday, December 08, 2015 11:39 AM
To: Kumar, Rita; Eagle, Venus
Cc: Carrie Daniels; Kelly Hoskins (Kelly.Hoskins@perrigo.com)
Subject: 2517-RTG Response
Attachments: 2517-RTG Response Letter 12-7-2015.pdf; 8570-1 Imid for Cats.pdf; 2517-RTG Revised Label 12-7-15 clean - FINAL.pdf; 2517-RTG Revised Label 12-7-15 - FINAL.pdf; EPA Reg No 11556-116 Highlighted.pdf; 2517-RTG label comments 12-7-2015 - FINAL.pdf; 8570-27 Imid for Cats.pdf

Dear Rita and Venus,

Please find attached Sergeant's response for 2517-RTG. It is our understanding that EPA will process the email submission. Please let me know if EPA requires a copy to be submitted to document processing.

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Exponent
1150 Connecticut Ave., NW
Suite 1100
Washington, DC 20036

telephone 202-772-4900
facsimile 202-772-4979
www.exponent.com

December 8, 2015

Venus Eagle
Product Manager 01
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

**Subject: Response to EPA PRIA Predecisional Letter for Sergeant's 9.1%
Imidacloprid Spot On for Cats (EPA File Symbol 2517-RTG)
Decision Number 498685**

Dear Ms. Eagle:

On behalf of Exponent's client, Sergeant's Pet Care Products, Inc. (Sergeant's), Exponent is responding to EPA's PRIA Predecisional Letter for Sergeant's 9.1% Imidacloprid Spot On for Cats (EPA File Symbol 2517-RTG) dated December 4, 2015. Sergeant's wants to work with EPA to complete this registration by the current PRIA due date of December 10, 2015. We request that EPA review our response and let us know if this is possible or if the Agency will require additional time under PRIA to review and respond.

Please find enclosed the following documents in support of this response:

- 8570-1 form;
- Updated product label (track changes and clean versions);
- Copy of EPA stamped approved label for EPA Reg. No. 11556-116 (highlighted to demonstrate EPA approved language); and
- Updated EPA Formulator's Exemption Form.

Sergeant's has reviewed EPA's label comments and has addressed each in the enclosed document. Based upon discussions with Ms. R. Kumar and Ms. M. Lewis our enclosed updated label and response document outline the following:

- EPA comments that have been addressed by updating the label
- Support language for those label claims that have not been included in the updated label

Please note that during our review of the Agency label comments on the Sergeant's 9.1% Imidacloprid Spot On for Dogs (EPA File Symbol 2517-RTU) and the Sergeant's 9.1% Imidacloprid Spot On for Cats (EPA File Symbol 2517-RTG), we noted label comments that

Venus Eagle
December 7, 2015
Page 2

were not consistent between the two labels. Based upon our review, we incorporated various label comments from each review to ensure consistency between the final labels.

If you have any questions regarding this submission, please contact me at jmessina@exponent.com or 202-772-4932.

Sincerely,

A handwritten signature in black ink, appearing to read 'J. Messina', with a long horizontal flourish extending to the right.

James Messina
Authorized Representative of
Sergeant's Pet Care Products, Inc.

Enclosures

cc: Rita Kumar, EPA
Marianne Lewis, EPA
Kelly Hoskins, Sergeant's
Carrie Daniels, Exponent

12/7/15 clean copy

Sergeant's® Master Label

07 December 2015

Version 15.1

EPA Reg. No. 2517-RTG

Information in [] is optional.

Information in { } is note to reviewer.

Page 1 of 9

FRONT PANEL

Cats Spot On Imidacloprid

[Optional text appears in brackets/parenthesis – the final label may include some or all of the optional text on front, back or side label panels]

Sergeant's® 9.1% Imidacloprid Spot On for Cats

{Market Label-the word Cat will be at least 40-75% in height of the largest letter in the primary brand name.}

{Market Label-a large clear picture of a cat in the respective weight range will be on the front panel of the label.}

{One of the following statements will appear on appropriate weight band market label front panel as required per Agency's pet spot-on mitigation measures:}

For use ONLY on cats [[&][and] kittens] [weighing] 2 [-][to] 9 lbs. and over 8 weeks [old][of age]

For use ONLY on cats [[&][and] kittens] [weighing] 2 [-][to] 9 lbs. and 8 weeks [of age] or older

For use ONLY on cats [[&][and] kittens] [weighing] [more than][over][>] 9 lbs. and over 8 weeks [old][of age]

For use ONLY on cats [[&][and] kittens] [weighing] [more than][over][>] 9 lbs. and 8 weeks [of age] or older

ONLY for cats [[&][and] kittens] over 8 weeks [old][of age] and [weighing] 2 [-][to] 9 lbs.

ONLY for cats [[&][and] kittens] 8 weeks [of age] or older and [weighing] 2 [-][to] 9 lbs.

ONLY for cats [[&][and] kittens] over 8 weeks [old][of age] and [weighing] [more than][over][>] 9 lbs.

ONLY for cats [[&][and] kittens] 8 weeks [of age] or older and [weighing] [more than][over][>] 9 lbs.

ACTIVE INGREDIENT:

Imidacloprid.....9.10%

OTHER INGREDIENTS:90.90%

[TOTAL] 100.00%

KEEP OUT OF REACH OF CHILDREN WARNING

See [Back][or][Side][Label[s]][Panel[s]] for Additional Precautionary Statements

NET CONTENT: X fl oz [Y – X fl oz applicators]

[0.014 fl oz (0.4 mL) [tubes][vials][applicators][pipettes]]

[0.027 fl oz (0.8 mL) [tubes][vials][applicators][pipettes]]

[ABNs]

[SENTRY® Vet for Cats Imidacloprid]

[SENTRY® Vet Advanced Flea for Cats]

[SENTRY® Vet FleaGuard for Cats]

[SENTRY® Vet Vantage for Cats]

[SENTRY® Vet Flea Vantage for Cats]

[SENTRY® Advanced for Cats Imidacloprid]

[SENTRY® Advanced FleaGuard for Cats]

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[SENTRY® Advanced Vantage for Cats]

[SENTRY® Advanced Flea Vantage for Cats]

[SENTRY® Advanced VetSpot for Cats]

[PetArmor® Vantage for Cats]

[PetArmor® Advant for Cats]

[PetArmor® FleaGuard for Cats]

[PetArmor® Advanced for Cats]

[PetArmor® Flea Vantage for Cats]

[PetArmor® Adv Flea for Cats]

[PetArmor® Adv.Flea for Cats]

[PetArmor® AdVet for Cats]

[Active Ingredient Reference Statements]

[Contains imidacloprid, [the] [same] active ingredient used in

{OR}

[Contains [the] [same] active ingredient used in

{OR}

[[Brand Name] [This product] contains imidacloprid, [the] [same] active ingredient used in

{OR}

*[Advantage® 9 Topical Solution] [Advantage® for Small Cats] [DefenseCare Flea Protection Small Cat] [Advantage® TM 9 (Imidacloprid) Topical Solution]. **

[Contains imidacloprid, [the] [same] active ingredient used in [Advantage® 18 Topical Solution] [Advantage® for Large Cats] [DefenseCare Flea Protection Large Cat] [DefenseCare Flea Protection Large Cats] [Advantage® 18 (Imidacloprid) Topical Solution].

**)*

[*[[Brand Name]][This product] is not manufactured or distributed by Bayer Healthcare LLC, the makers of

*[Advantage® 9 Topical Solution] [Advantage® for Small Cats] [DefenseCare Flea Protection Small Cat] [Advantage® TM 9 (Imidacloprid) Topical Solution]. **

*[Contains imidacloprid, [the] [same] active ingredient used in [Advantage® 18 Topical Solution] [Advantage® for Large Cats] [DefenseCare Flea Protection Large Cat] [DefenseCare Flea Protection Large Cats] [Advantage® 18 (Imidacloprid) Topical Solution]. **

[[[Advantage® 9 Topical Solution] [Advantage® for Small Cats] [DefenseCare Flea Protection Small Cat] [Advantage® TM 9 (Imidacloprid) Topical Solution] is a registered trademark of Bayer Healthcare LLC.]*

[[[Advantage® 18 Topical Solution] [Advantage® for Large Cats] [DefenseCare Flea Protection Large Cat] [DefenseCare Flea Protection Large Cats] [Advantage® 18 (Imidacloprid) Topical Solution]*

is a registered trademark of Bayer Healthcare LLC.]

[Fleas]

[Prevents further flea infestation for [[four][4] weeks][1 month] with one treatment]

[Prevents further flea infestation for [[four][4] weeks][1 month] with one application]

[Brand Name] Prevents further flea infestation for [four][4] weeks][1 month]

[Kills fleas within 12 hours [of application] on cats]

[Kills reinfesting fleas within 2 hours]

Sergeant's® Master Label

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[Kills [adult] fleas before they lay eggs]

[[Brand Name][This product] kills fleas and may reduce the incidence of a hypersensitivity skin disorder called flea allergy dermatitis (FAD), which may be caused by the feeding activity of fleas on cats.]

[Kills flea larvae in cat's environment following contact with treated cat]

[Apply monthly [for optimal flea control]]

[Apply monthly [to control and prevent fleas]]

[Kills fleas]

[Kill fleas in 12 hours, continues to kill for 4 weeks]

[Kills fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation]

[Kills fleas, which may be a source of flea allergy dermatitis, in 12 hours]]

[Stops and prevents infestation of listed pests for 4 weeks]

[Use [of Brand Name][of this product] kills fleas and may reduce incidence of flea bite hypersensitivity [and][or] [flea allergy dermatitis] [FAD]]

[Use [of Brand Name][of this product] kills fleas and may reduce incidence of [flea bite hypersensitivity] [and][or] flea allergy dermatitis [FAD]]

[Monthly treatment [with Brand Name][with this product] kills fleas and may reduce incidence of [flea bite hypersensitivity] [and][or] flea allergy dermatitis [FAD]]

[Monthly treatment [with Brand Name][with this product] kills fleas and may reduce incidence of flea bite hypersensitivity [and][or] [flea allergy dermatitis] [FAD]]

[Flea protection]

[Active against fleas]

[Kills fleas on [kittens and] cats]

[[Brand Name] Offers protection against fleas]

[Flea control for cats and kittens [over 8 weeks [old]][of age]]

[Flea control for cats and kittens [8 weeks [of age] or older]]

[Kills fleas within 12 hours on cats [and prevents further infestations for [up to] [[4][four] weeks][[1][one][a] month]]

[All Others]

[Apply to [cats and] kittens over 8 weeks old]

[Apply to [cats and] kittens 8 weeks or older]

[SENTRY®]

[PetArmor®]

[[Sergeant's] Caring For Your Pets Since 1868]

[Specially Formulated for Cats and Kittens [Over 8 Weeks [Old]][of Age]]

[Specially Formulated for Cats and Kittens [8 Weeks [of Age] or Older]]

[Cats and Kittens [over 8 weeks [old]][of age]]

[Cats and Kittens [8 weeks [of age] or older]]

[Use only on kittens [over 8 weeks [old]][of age]]

[Use only on kittens [8 weeks [of age] or older]]

[The Only Monthly Flea Protection You Need For Your Cat[s]!]

[Convenient]

[Easy application]

[Easy to apply product]

[Easy to Use [Application]]

[One Step Hassle Free Protection!]

[Waterproof]

[Remains effective, even after [bathing,][shampooing,] swimming, or exposure to sunlight]

Sergeant's® Master Label

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[and][or] [rain]

[Remains effective, even after [bathing,][shampooing,] water immersion, or exposure to

[sunlight] [and][or] rain]

[Once a month treatment]

[Apply once every [4 weeks] [month] [30 days]!]

[4 Week Dose!] [1 Month Dose!] [30 Day Dose!]

[For year-round protection, apply [Brand Name][this product] monthly]

[Best if used year round!]

[X Applications] [X Week Supply] [X Month Supply]

[One Application] [4 Week Supply] [1 Month Supply]

[Two Applications] [8 Week Supply] [2 Month Supply]

[Three Applications] [12 Week Supply] [3 Month Supply]

[Four Applications] [16 Week Supply] [4 Month Supply]

[Five Applications] [20 Week Supply] [5 Month Supply]

[Six Applications] [24 Week Supply] [6 Month Supply]

[9 Applications] [36 Week Supply] [9 Month Supply]

[12 Applications] [52 Week Supply] [12 Month Supply]

[24 Applications] [104 Week Supply] [24 Month Supply]

[[for] Small Cat[s] [2 to 9 lbs.]]

[[for] Large Cat[s] [Over 9 lbs.]]

[Direct to skin [tube][vial][applicator][pipette]]

[Easy to Use] [tube][vial][applicator][pipette]

[Clean cut [open] [tube][vial][applicator][pipette]]

[No-mess [open] [tube][vial][applicator][pipette]]

[Clip-tip design [tube][vial][applicator][pipette][!]]

{END – FRONT PANEL}

BACK PANEL/SIDE PANEL OR INSERT

Cats Spot On

Imidacloprid

[The active ingredient in [Brand Name][this product] is [imidacloprid,] formulated for fast acting [and long lasting] control of fleas on cats.] [[Brand Name][This product] kills fleas within 12 hours and prevents further flea infestations for [up to] [[4][four]weeks][1][one] month][30 days].]

READ ENTIRE LABEL BEFORE EACH USE.

USE ONLY ON CATS AND KITTENS 8 WEEKS OF AGE OR OLDER.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. WARNING. Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Harmful if swallowed. Avoid contact with skin. Wash hands thoroughly with soap and warm water after handling.

HAZARDS TO DOMESTIC ANIMALS. For external use on cats only. Individual sensitivities, while rare, may occur after using ANY pesticide product for cats. Do not treat your cat with more than one pesticide product at a time. Over dosing your cat can result in serious illness and even death. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing cats.

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FIRST AID

If In Eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If Swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If on Skin or Clothing	<ul style="list-style-type: none">• Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-781-4738 for emergency medical treatment information.

NOTE TO PHYSICIAN

Treat the patient symptomatically.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR CAT, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

Restrictions:

- Do not use on animals other than cats.
 - Do not allow your cat to ingest this product.
 - Do not use on kittens under 8 weeks of age. Do not apply to cats weighing less than 2[9] lbs.
 - Use entire contents of tube[vial][applicator][pipette] on each cat. Do not split one tube[vial][applicator][pipette] between two cats. Do not use multiple tube[vial][applicator][pipette]s on one cat.
 - Weigh your cat to be sure you are applying the right dose formulated for the weight of your cat.
 - Separate the treated cat from all other cats and dogs for 24 hours after treatment has been applied.
- Do not have contact or allow children to have contact with the treated area until completely dry.

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{Side Effects box to be located on label on the lower right hand side of the back panel}

Side Effects: Monitor your cat after application. [Some cats may experience temporary startle effects when any product is applied.] Cats may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe your cat with a mild soap and rinse with large amounts of water. If these or other side effects occur, consult your veterinarian or call 1-800-781-4738. If your cat has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your cat and continue to monitor your cat for the next 24 hours.

{OUTER PACKAGING}

How to open: Remove product [tube[s]][vial[s]][applicator[s]][pipette[s]] from the package. [Separate one [tube][vial][applicator][pipette] from the others.] Hold the [tube][vial][applicator][pipette] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply: While holding the cat with one hand, use the other hand to apply the solution. Invert the [tube][vial][applicator][pipette] and use the narrow end to part the cat's hair. Apply contents of one [tube][vial][applicator][pipette] of [Brand Name] [this product] to the cat's skin, as directed below. When finished, wrap the [tube][vial][applicator][pipette] in paper and put into the trash. Only one [tube][vial][applicator][pipette] per treatment is needed.

{For cartons containing 0.4 mL (0.014 fl oz) applicator tubes}

Only For Cats Weighing 2[-][to] 9 lbs. Do not apply to cats weighing less than 2 lbs.

[including small cats or kittens, only 8 weeks or older] Apply one [tube][vial][applicator][pipette] 0.4 mL (0.014 fl oz) [directly to skin] as a spot between the shoulder blades. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat.

{For cartons containing 0.8 mL (0.027 fl oz) applicator tube}

Only For Cats Weighing Over 9 lbs. Do not apply to cats weighing less than 9 lbs. Apply one [tube][vial][applicator][pipette] 0.8 mL (0.027 fl oz) [directly to skin] as a spot between the shoulder blades. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat.

FREQUENCY OF APPLICATION

[Use [Brand Name {or} this product] monthly for control of flea[s] [infestations].]
[[Studies show that] [Brand Name {or} This product] kills fleas within 12 hours of application and [lasts {or} protects] [for [up to] [[four][4] weeks][30 days][one month].]
[[Brand Name {or} This product] kills reinfesting fleas within [2][two] hours and prevents further infestations of fleas [for [up to] [[four][4] weeks][30 days][one month]].]
[If your cat is at high risk for flea reinfestation [,or in a highly infested environment], apply monthly.]
[Apply monthly for optimal flea control.]
[[Brand Name {or} This product] is waterproof and remains effective, even after water immersion or exposure to sunlight [and][or] [rain].]
[Allow treated area to dry thoroughly.]

Sergeant's® Master Label

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Version 15.1

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[Do not reapply for [[four][4] weeks][30 days].]

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove [tube][vial][applicator][pipette] from pack until ready to use. Store in a cool (below 77°F/[25°C]), dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

CONTAINER DISPOSAL: If **empty:** Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. If **partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[WARRANTY

Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. The directions for use of this product are believed to adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer. Sergeant's is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Sergeant's, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: [Sergeant's][SENTRY][PetArmor®] Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

[Satisfaction Guaranteed][If you are not satisfied, we will make it right with a replacement or refund.]

In Case of Emergency, call: 1-800-781-4738
Non-Emergency, call: 1-800-224-PETS (7387)

[Coupon(s) inside or on outside of box]
[Made in USA[with Global Materials]]

[Distributed by:] [Manufactured by:]
Sergeant's Pet Care Products, Inc.
Omaha, NE 68138-3710

EPA Reg. No. 2517-RTG
EPA Est. No. XXXXX-XX-XX
[BAR CODE AREA]

{END - BACK/SIDE PANEL OR INSERT }

{START – OPTIONAL PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT PACKAGE OR INSERT}

[How to Apply – May contain graphics illustrating product use, e.g., cat with a drop falling onto its neck from a tube/vial on front, side, or back carton label and/or applicator labeling.]

[Clip. Part. Squeeze.]

Easier-than-ever applicator lets you *clip* the tip, *part* the fur and *apply* directly to the skin – putting proven flea protection where it needs to be.]

Sergeant's® Master Label

07 December 2015

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[Application Instructions]

How to Open:

1. Remove product tube[s][vial[s]][applicator[s]][pipette[s]] from the package.
2. Separate one tube[vial][applicator][pipette] from the others. Hold the tube[vial][applicator][pipette] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply:

1. Invert tube[vial][applicator][pipette] over cat and use open end to part cat's hair.
2. Apply contents of one tube[vial][applicator][pipette] [of] [Brand Name] as a spot between the shoulder blades. Squeeze tube firmly to apply all of the solution to the cat's skin.

[Look at the Label (Look at the Label icon) [Easy] 6 Step [Easy] [Spot On] [Squeeze-On] [Topical] Checklist]

- [1] Read the label completely and follow directions
- [2] Weigh your cat
- [3] Do NOT use dog products on cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals after treatment [application] to avoid chance of ingestion
- [6] Do NOT split tube[vial][applicator][pipette] between cats[and use the ENTIRE [tube][vial][applicator][pipette] contents]

[Brand Name][This product]

[Monthly reminder card]

[1][2][3][4][5][6][12][24][Month [Treatment] [Application] Tracker][Carecard]

[For year round protection apply [Brand Name][this product] monthly.]

[Cat's Name (Empty blank for owner to fill in name)]

[Cat's Weight (Empty blank for owner to fill in name)]

[First][1st] [Second][2nd] [Third][3rd] [Fourth][4th] [Fifth][5th] [Sixth][6th] [Seventh][7th]

[Eighth][8th] [Ninth][9th] [Tenth][10th] [Eleventh][11th] [Twelfth][12th]

[Dose] [Treatment] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)

[Application Date] [Date of Application]

[Calendar stickers with [Brand Name]

[Place stickers on your calendar as a reminder to reapply [Brand Name][this product] in 30 days.]

[Monthly Application Reminder Magnet (image of reminder magnet)]

[Place sticker on your calendar [or refrigerator] to remind yourself to apply [Brand Name][this product] to your cat]

[33% More Free]

[Bonus Size]

[Buy 3 get 1 free]

[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days, the reminder light will blink, reminding you to reapply [Brand Name][this product]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

Sergeant's® Master Label

07 December 2015

Version 15.1







EPA Reg. No. 2517-RTG

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Information in { } is note to reviewer.

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[Each optional graphic below may or may not appear anywhere on the finished label]

	Adult Flea	
	Fleas	
	Flea Larvae	



Adm Flea



MADE IN THE
USA

MADE IN THE
USA
WITH GLOBAL MATERIALS

{END – OPTIONAL PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT
PACKAGE OR INSERT }
TUBE/VIAL LABEL

Cats Spot On
Imidacloprid

{Front Label}

{Back Label}

[Brand Name (for Cats)]

[X-Y] lbs. ≥8 wks

Imidacloprid 9.10%

0.014 fl oz (or) 0.027 fl oz {label code}

{EPA REG No may be on either the front or back label}

{END – TUBE/VIAL LABEL}

KEEP OUT OF REACH OF CHILDREN

WARNING: Read directions and precautions
before using. Use scissors to open.

EPA REG. No. 2517-RTG {label code}



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

December 4, 2015

James B. Messina
Authorized Agent for
Sergeant's Pet Care Products, Inc.
c/o Exponent, Inc.
1150 Connecticut Avenue, NW
Suite 1100
Washington, DC, 20036

Subject: PRIA Predecisional letter – New product registration
Product Name: Sergeant's 9.1% Imidacloprid Spot On for Cats
EPA File Symbol: 2517-RTG
Decision Number: 498685

Dear Mr. Messina:

The Agency has completed its review and assessment of your application pursuant to Section 33(b)(3) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended by the Pesticide Registration Improvement Extension Act of 2012. The Agency has made a pre-decisional determination that your application cannot be approved unless revisions are made to the draft label dated March 2, 2015. The necessary label changes are specified on the attached document.

Since there is limited time before the PRIA Decision Due Date expires, it is important to discuss any objections you have to these changes immediately and whether you will need to submit additional data for review. If these discussions determine that submitting data will be necessary, the PRIA decision due date may need to be renegotiated to allow sufficient time to address and resolve such differences. If the PRIA Decision Due Date is not renegotiated, and the label issues are not resolved before the PRIA Decision Due Date, the Agency will send a follow-up letter that will represent the Agency's decision to close out the PRIA decision review time. The follow-up letter will provide the following three options for continuing the review of the application:

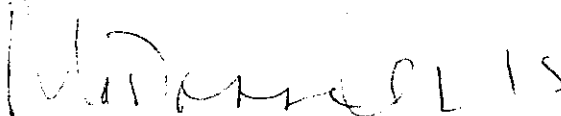
- a. You agree to all of the terms associated with the draft accepted label as revised by the Agency and request that it be issued as the accepted final Agency-stamped label; or
- b. You do not agree to one or more of the terms of the draft accepted label as revised by the Agency and request additional time to resolve the difference(s); or
- c. You withdraw the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee.

If you inform EPA that you have concerns as described under (b) above, you will have up to 30 calendar days from the date of that follow-up letter to reach agreement with the Agency on the final version of the label that the Agency will accept. If an agreement cannot be reached within those 30 days, EPA would intend to proceed with denial of the application.

If you agree to all of the terms of the accepted label as described in (a) above, or if you and EPA resolve any differences as described in (b), you must submit a revised label to EPA. EPA will then provide an accepted final Agency stamped label to you within 2 business days following your written electronic confirmation of agreement to the Agency including the revised label to be stamped.

If you have any questions, please contact Rita Kumar at kumar.rita@epa.gov or (703) 308-8291.

Sincerely,



Venus Eagle, Product Manager 01
Invertebrate and Vertebrate Branch 3
Registration Division (7505P)
Office of Pesticide Programs

Attachment (1)

Attachment for Predecisional letter for 2517-RTG

Label Comments for 2517-RTG (Sergeant's 9.1% Imidacloprid Squeeze On for Cats)

1. Alternate Confidential Statement of Formula #3 is not acceptable, because the source product is much different from source product in the basic formulation. Submit a revised Formulator's Exemption statement deleting the source product given in alternate formulation #3.
2. Indicate intended use(s) on the front panel, below product name.
3. On page 2, the referral statement for additional precautionary statements cannot be optional. Remove brackets from the entire statement. As per the 2011 pet spot-on mitigation revise "...]] for Additional Precautionary Statements]" to read "...]] for First Aid, Precautionary Statements, and Directions for Use."
4. Clearly indicate which text appears on front, back or side panels per the 2011 pet spot-on mitigation.
5. On page 2 and elsewhere, remove the comparative statements "[same]" & "Compare to....." In reference to other companies products. Only include factual, non-comparative statements such as "Contains the active ingredient used in"
6. On page 3 and elsewhere, delete *, [* or [*]. These asterisks do not refer to any footnotes. The asterisk may not be used as a placeholder for other unspecified products as the Agency must verify that any listed product(s) contain the same a.i. at the same percentage.
7. Please move any marketing claims to the end of the draft label (prior to the optional graphics) for better clarity in the label.
8. As per the efficacy review delete the following "Fleas" marketing claims:
 - Prevents further flea infestation for four weeks/1 month with just one treatment (can rewrite to read "Prevents further fleas infestation for up to four(4) weeks with one treatment"
 - Prevents further flea infestation for four weeks/1 month with just one application (can rewrite to read "Prevents further fleas infestation for up to four(4) weeks with one application"
 - Kills fleas within 12 hours [of application]
 - Kills reinfesting fleas within 2 hours
 - Targets all life stages
 - Kills adult fleas before they lay eggs
 - Kills flea larvae in cat's environment following contact with treated cat (This claim would require efficacy data)
 - Prevents flea infestation for four (4) weeks/1 month
 - Complete flea protection
 - Complete flea control
 - Optimal flea control
 - Optimal flea protection
 - Advanced flea protection
 - Advanced flea control

- Kills fleas within 12 hours on cats [and prevents infestations for up to 4 four weeks 1 one a month]
9. Delete the following “Other” marketing claims:
 - Delete “Specially” from “Specially formulated....” statements
 - Original vet strength (this is false and misleading, this or a similar formulation has been in the market for many years)
 - Fast acting long lasting (these are enhanced efficacy claims, must be supported by efficacy data and specific length of time)
 - Waterproof
 - Remains effective even after bathing, shampooing, water immersion, or exposure to sunlight [and][or][rain]
 - Remains effective, even after bathing, shampooing water immersion, or exposure to [sunlight][and][or][rain]
 - Best if used year round! (this statement is too broad and unspecific)
 - Flea life cycle icon/diagram listed on p 9
 - All claims relating xx number of applications to xx weeks supply (these do not match the once a month application direction)
 - Change “Can be used” to “Use only on kittens”
 - The only flea protection you need for your cats (or qualify this by adding “...when applied monthly [every 30 days])
 10. On page 5 in the “Precautionary Statements” revise the ‘Hazards to Humans’ to read:

“Warning. Causes substantial but temporary eye injury. **Harmful if swallowed. Harmful if absorbed through skin.** Do not get in eyes or on clothing. Avoid contact with skin. Wash hands **after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.**” (changes indicated in **bold**)
 11. Under the Directions for Use, add a separate heading “Restrictions:” and place all the “Do not” statements under this separate heading “Restrictions”.
 12. On page 6, directly after the sentence “Separate the treated... has been applied” add “Do not have contact or allow children to have contact with the treated area until completely dry.”
 13. On page 6, under “{for cartons containing 0.4 mL ...tubes}” & under “{for carton containing 0.8 ...tubes}” delete the [] from around “Do not apply to cats weighing less than 2 lbs” – this is NOT an optional statement.
 14. On page 6, in the claims directly below “Frequency of application” as per the efficacy review delete “This product] kills within 12 hours of application”
 15. On page 6, in the claims directly below “Frequency of application” as per the efficacy review delete “This product] kills reinfesting fleas within 2 hours”
 16. On page 5, the header “Directions for Use” must be in a larger font and more prominent (e.g., underlined) to ensure that it is clear to user that everything that follows falls under this heading.
 17. On page 7, as per efficacy review directly above the Storage and Disposal statements delete the claim “[brand name {or} this product] is waterproof and remains effective, even after water immersion or exposure to sunlight [and][or][rain].]”
 18. On page 7, place the Storage and Disposal statement inside a solid line box.

19. On page 8, revise “[Application Instructions][Directions for Use]” to just read “Application Instructions” – Directions for Use is the header for all of this – can’t use the header twice.
20. On page 8, under “How to Open” - #2 revise “[Separate one...the others]” to read “Separate one... the others” (took outside brackets off since it appears you need to separate out one tube from the others ...)
21. Delete the icon Satisfaction Guaranteed, or qualify it with “or your money back”.
22. Delete the icon Made in the USA since the alternate source [REDACTED]
23. Per the implementation of label changes to pet spot on products in 2011:
 - a. The Front Panel is to have a large clear picture of a cat in the weight range for the product as packaged;
 - b. The Back Panel: Place the box labeled “Side Effects” at the lower right hand corner of the back panel.

Product ingredient source information may be entitled to confidential treatment



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: Rita Kumar

From: Jacquelyn Marchese, Entomologist

Jacquelyn Marchese

Secondary Review: Kevin Sweeney, Senior Entomologist

Kevin J. Sweeney

Date: November 12, 2015

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD (DER)

~~THIS DER DOES CONTAIN CONFIDENTIAL BUSINESS INFORMATION - DO NOT RELEASE TO REGISTRANT~~

Note: MRIDs found to be unacceptable to support label claims should be removed from the data matrix.

DP barcode: 427072

Decision no.: 498685

Submission no: 962065

Action code: R315

Product Name: Sergeant's 9.1% Imidacloprid Spot On for Cats

EPA Reg. No or File Symbol: 2517-RTG

Formulation Type: pet spot-on, liquid

Ingredients statement from the label with PC codes included:

9.1% imidacloprid PC: 129099

Application rate(s) of product and each active ingredient (lbs. or gallons/1000 square feet or per acre as appropriate; and g/m² or mg/cm² or mg/kg body weight as appropriate):

Weight of cat (lb)	Amount of product (mL)	kg of cat	mL/kg of imidacloprid	Mg/kg of product	Mg/kg of imidacloprid
2-9	0.4	0.91-4.08	0.004-0.016	193.5-470.3	9.8-42.8
9+	0.8	4.08	0.018	215.1	19.6

Use Patterns: This product is to be applied to cats over the age of 8 weeks, weighing over 2 lbs. The label directs the user to apply the product as a spot on the cat's back between the shoulder blades.

I. Action Requested: The proposed label has public health claims of kills fleas, controls/kills fleas for up to one month, etc. The reviewer requested that the seven submitted efficacy studies be reviewed to determine their applicability in support of the new product and the proposed label claims.

Provide details regarding what the reviewer/registant requested (e.g., pests and claims, how many studies)

II. Background: The registrant has cited seven previously reviewed efficacy studies to support the registration of this new product and the claims against fleas.

III. MRID Summary:

43679503. Cunningham, J. 1995. Efficacy Evaluation of Bay t 7391 (Imidacloprid) 10% Solution Applied Dermal for Control of Fleas on Cats.

(1) GLP

(2) **Methods:** On day -5 each cat was infested with 50 fleas. Each cat was combed and fleas were counted on day -4. The number of fleas recovered during the day -4 comb out demonstrated the cat's natural ability to harbor a population of fleas. Based on this ability, 15 cats were then assigned into 3 groups, evenly spreading the ability of flea harborage between the groups, therefore 5 animals were assigned to each group. On day -1 cats were again infested with 50 fleas. On test day 0, group 1 received a treatment of 3.75 mg/kg* of imidacloprid, group 2 received 7.5 mg/kg of imidacloprid and group 3 cats served as the untreated control and received a blank solution. The products were applied to the skin of each cat between the shoulder blades, using a syringe. The study lasted for 35 days. During this time, cats were infested on days -1, 6, 13, 20, 27, 34, and were fleas were combed out and counted on days 1, 7, 14, 21, 28, and 35.

*Note to future reviewer, the unit rate is incorrectly stated as mL/kg in the study.

(3) Results:

Group	ID	Weight	Pre-Fleas	Post-Tx Flea Counts (days)					
				1	7	14	21	28	35
0 mg/kg	454	4.6	33	33	42	41	43	46	48
0 mg/kg	458	3.4	36	37	26	33	51	31	37
0 mg/kg	463	5	31	30	48	45	48	39	38
0 mg/kg	469	4.9	40	50	55	51	53	44	40
0 mg/kg	487	3.9	36	39	42	31	44	31	36
3.75 mg/kg	453	3.9	52	0	10	12	33	21	20
3.75 mg/kg	468	4.6	33	0	0	24	27	39	18
3.75 mg/kg	476	5	32	0	0	0	9	4	5
3.75 mg/kg	477	5	37	0	4	0	20	11	32
3.75 mg/kg	484	3.7	35	0	3	5	21	13	15
7.5 mg/kg	459	5.4	38	0	0	0	1	9	2
7.5 mg/kg	460	3.9	36	0	1	4	19	26	10
7.5 mg/kg	465	3.4	31	0	0	4	22	11	28
7.5 mg/kg	467	6.1	35	0	2	2	3	6	10
7.5 mg/kg	488	3	33	0	3	2	32	31	35

Table 1. Flea counts by individual animal

DAY	GROUP 1 3.75 mg/kg		GROUP 2 7.5 mg/kg		GROUP 3 UNTREATED
	TOTAL	CONTROL	TOTAL	CONTROL	TOTAL
1	0	100	0	100	189
7	17	92.0	6	97.2	213
14	41	79.6	12	94.0	201
21	110	54.0	77	67.8	239
28	88	53.9	83	56.5	191
35	90	54.8	85	57.3	199

Table 2. Total group flea counts and percent flea control

(4) **Conclusion:** This study is **unacceptable** because the tested product only killed 90% or more of fleas for the first 14 days at both doses. Ninety percent efficacy should be demonstrated for a minimum of 28 days to support the proposed label. Further, the Agency recommends that each test group includes a minimum of 6 animals to provide statistically relevant results.

43679504 Cruthers, L. 1995. Efficacy Evaluation of Bay t 7391 (Imidacloprid) 10% Solution Applied Dermally for Control of Fleas on Cats.

(1) GLP

(2) **Methods:** After a pre-test that evaluated each cat's natural ability to harbor a natural population of fleas, 30 cats were assigned into 3 groups, evenly spreading the ability of flea harborage between the groups. On day -1 cats were again infested with 50 fleas. On test day 0, group 1 received a treatment of 10 mg/kg of imidacloprid, group 2 received 20 mg/kg of imidacloprid and group 3 cats served as the untreated control and received a blank solution. The products were applied to the skin of each cat between the shoulder blades, using a syringe. The study lasted for 35 days. During this time, cats were infested on days -1, 6, 13, 20, 27, 34, and were fleas were combed out and counted on days 1, 7, 14, 21, 28, and 35. Efficacy was calculated by the following formula:

$$\frac{(\text{Mean number of live fleas on controls} - \text{mean number of live fleas on treated group}) * 100}{\text{Mean number of live fleas on controls}}$$

(3) **Results:**

TEST DAY 1 LIVE FLEA COMB COUNTS AND PRODUCT EFFICACY

GROUP	CAT NO.	TOTAL NO. LIVE FLEAS	PERCENT EFFICACY
1	5523	0	
1	4316	0	
1	7619	0	
1	5581	0	
1	5582	0	
1	1340	0	
1	5552	0	
1	938LC1	0	
1	5405	0	
1	3493	0	
	MEAN	0	100%
2	8645	0	
2	8657	0	
2	3347	0	
2	5530	0	
2	5536	0	
2	3494	0	
2	7632	0	
2	5575	0	
2	3119	0	
2	8652	0	
	MEAN	0	100%
3	5571	21	
3	94AXD1	42	
3	5580	35	
3	5598	38	
3	6376	50	
3	6914	37	
3	8648	34	
3	5576	23	
3	5573	47	
3	7409	37	
	MEAN	36.4	-

1= 10% SOLUTION IMIDACLOPRID AT 10.0 MG/KG, 2= 10% SOLUTION IMIDACLOPRID AT 20.0 MG/KG, 3= SOLVENT CONTROL

TABLE 4

TEST DAY 14 LIVE FLEA COMB COUNTS AND PRODUCT EFFICACY

GROUP	CAT NO.	TOTAL NO. LIVE FLEAS	PERCENT EFFICACY
1	5523	6	
1	4316	0	
1	7619	0	
1	5581	1	
1	5582	1	
1	1340	3	
1	5552	5	
1	93BLC1	2	
1	5405	6	
1	3493	0	
	MEAN	2.4	93.3%
2	8645	0	
2	8637	0	
2	3347	0	
2	5530	13	
2	5536	2	
2	3494	0	
2	7632	0	
2	5575	3	
2	3119	1	
2	8652	0	
	MEAN	1.9	94.7%
3	5571	42	
3	94AXD1	28	
3	5580	36	
3	5598	48	
3	6376	39	
3	6914	27	
3	8648	43	
3	5576	38	
3	5573	29	
3	7409	26	
	MEAN	35.6	-

1= 10% SOLUTION IMIDACLOPRID AT 10.0 MG/KG, 2= 10% SOLUTION
IMIDACLOPRID AT 20.0 MG/KG, 3= SOLVENT CONTROL

TABLE 5
TEST DAY 21 LIVE FLEA COMB COUNTS AND PRODUCT EFFICACY

GROUP	CAT NO.	TOTAL NO. LIVE FLEAS	PERCENT EFFICACY
1	5523	11	
1	4316	0	
1	7619	20	
1	5581	17	
1	5582	25	
1	1340	8	
1	5552	15	
1	93BLC1	0	
1	5405	21	
1	3493	13	
MEAN		13.0	70.7%
2	8645	0	
2	8657	4	
2	3347	0	
2	5530	26	
2	5536	17	
2	3494	0	
2	7632	2	
2	5575	12	
2	3119	11	
2	8652	4	
MEAN		7.6	82.8%
3	5571	43	
3	94AXD1	48	
3	5580	47	
3	5598	40	
3	6376	45	
3	6914	41	
3	8648	41	
3	5676	38	
3	5573	50	
3	7409	50	
MEAN		44.3	-

1= 10% SOLUTION IMIDACLOPRID AT 10.0 MG/KG, 2= 10% SOLUTION IMIDACLOPRID AT 20.0 MG/KG, 3= SOLVENT CONTROL

(4) **Conclusion:** This study is unacceptable because the tested product only killed 90% or more of fleas for only the first 14 days. Ninety percent efficacy should be demonstrated for a minimum of 28 days to support the proposed label.

43794101. Hopkins, T., Kerwick, C., Coodley, I. 1995. Efficacy Evaluation of Bay t 7391 (Imidacloprid) 10% Solution Applied Dermal for control of Adult Fleas and Flea Eggs on Cats.

(1) non-GLP

(2) **Methods:** Approximately 100 unfed fleas were applied on the sacrum of each cat. Cats were infested on days 5, 7, 12, and 15 before treatment to determine each cat's natural ability to harbor a flea population. Based on the determined ability, cats were ranked and assigned to one of two groups, where the ability to harbor fleas was equally spread between groups. Cats were then infested again a day before treatment (day -1). On the day of treatment, cats were treated with 10 mg/kg of imidacloprid or a blank formulation to the top of the neck and were reinfested with 100 fleas on days 6, 13, 20, and 27 days after treatment. Fleas were spot counted by hand immediately before treatment, on day after treatment and then fleas were counted one day after each subsequent infestation.

During this trial, cats were housed in individual cages with egg collection trays under the flooring. Flea eggs were collected 4 days before treatment and again on 2, 9, 16, 23, and 30 days after treatment. Eggs that were not brown, desiccated, shriveled, or those which had already hatched were not included in the count.

(3) Results:

Table 2: Number of *Ctenocephalides felis* counted on cats

Chemical name and formulation & batch.	Dosage and Application	Cat Number	Pre-treatment Flea Count	Post Treatment Flea Counts					
				Days after treatment					
				1	7	14	21	28	
		326	21	1	0	1	0	1	
		74	30	0	0	2	1	1	
Bay 7391	10mg/kg	392	10	0	0	0	2	1	
10 % w/v		208	23	0	0	0	0	0	
Spot On	Dermal,	331	35	0	0	2	3	6	
	one spot	289	29	0	1	1	1	0	
	midline top	60	25	0	0	0	1	1	
	of neck	187	24	0	0	0	0	0	
		114	46	0	1	0	0	0	
		334	36	0	0	0	1	0	
Average Flea Counts			28.6	0.1	0.2	0.6	0.9	1	
		136	33	26	24	28	33	31	
		427	22	11	13	13	14	12	
		342	47	26	24	31	41	33	
	Untreated	1	15	13	27	14	16	18	
		466	30	16	23	24	47	47	
		425	26	36	19	22	21	20	
		73	23	23	19	10	16	13	
		9	39	21	34	23	17	21	
		407	28	10	30	10	19	20	
		415	25	15	1	20	14	25	
Average Flea Counts			28.8	19.7	23	19.5	23.8	23.4	

Table 3: Efficiency of Bay 7391 in the reduction of *Ctenocephalides felis* when compared to untreated cats

	Days before or after treatment					
	-1	+1	+7	+14	+21	+28
Average flea count on treated cats	28.6	0.1	0.2	0.6	0.9	1
Average flea count on untreated cats	28.8	19.7	23	19.5	23.8	23.4
Efficiency of flea reduction		99.5%	99.1%	96.9%	96.2%	95.7%

Table 4: Counts of flea eggs dropping from treated and untreated cats.

Chemical name and formulation & batch number.	Cat Number	Pre-treatment Flea Egg Counts*	Post Treatment Flea Egg Counts* (72 hours after reinfestation)				
			Days after treatment				
			2	5	16	23	30
Bay 7391 10 % w/v Spot on Dermal one spot midline top of neck	326	176	0	0	0	0	0
	74	214	5	0			
	392	197	2	0	0	1	
	208	96	4	0	0	0	0
	331	68	1	0	0	0	2
	289	256	8	0	0	0	24
	60	118	1	0	0	0	6
	187	192	3	0	0	0	0
	114	56	0	0	0	0	0
	334	203	10	0	0	0	0
Average Flea Egg Counts		157.8	3.4	0	0.2	0.1	3.7
Untreated	136	80	278	369	202	322	175
	427	137	95	4	59	51	118
	342	311	327	386	271	317	350
	1	130	265	198	174	163	124
	466	226	197	278	254	399	217
	425	140	205	299	197	180	121
	73	181	293	300	178	212	175
	9	222	400	269	198	147	252
	407	89	71	148	61	51	112
	415	95	146	177	92	112	80
Average Flea Egg Counts		161.1	227.7	242.8	168.6	187.5	172.4

Table 5: Efficiency of Bay 7391 in the reduction of *Ctenocephalides felis* eggs when compared to untreated cats

Average flea egg count on treated cats	Days before or after treatment					
	-4	+2	+9	+16	+23	+30
Average flea egg count on treated cats	157.8	3.4	0	0.2	0.1	3.7
Average flea egg count on untreated cats	161.1	227.7	242.8	168.6	187.5	172.4
Efficiency of flea egg reduction		98.5%	100%	99.9%	99.9%	97.8%

(4) **Conclusion:** This study is **acceptable** and supports that when imidacloprid is applied at 10 mg/kg to a cat, it will kill fleas for 30 days. The study also supports that when applied at 10 mg/kg to cats, imidacloprid reduces flea eggs.

43794102. Controlled Field Trials on the Efficacy and Tolerance of a Spot-On Formulation of Imidacloprid (BAY NTN 33893) 10% for Control of the Cat Flea (*C. felis*) in Domestic Cats

(1) non-GLP

(2) **Methods:** Twenty-seven, male and female domestic cats between the ages of 6 months and 4 years were utilized for this study. Each cat was infected with a naturally occurring population of cat fleas. An untreated control group of cats was not included in this study.

(3) **Results:** The results are not applicable as no untreated control group was included in this study.

(4) **Conclusion:** this study is **unacceptable** and does not support any claims as it does not include an untreated control group.

44256901. Cruthers, L.; 1997. Comparative Evaluation of How Quickly Advantage and Frontline (Fipronil) Top Spot Kill Fleas on Dogs

(1) GLP

(2) **Methods:** Thirty adult, mix-breed dogs of both sexes were selected for the study. Dogs were separated into 3 groups of 10 (X, Y, or Z). On test day 0 each group received a different treatment. Members of group X received Advantage (9.1% Imidacloprid), group Y received Frontline Top Spot (9.7% fipronil) and members of Group Z received the Advantage blank vehicle. The products were applied to the dogs per the labeled application rate. The application rate of Advantage mimicked the application rate of the proposed product (minimum of 0.008 mL/kg). On days -1, 6, 13, 20, and 27 dogs were infested with approximately 100 adult cat fleas. Two dogs from each group were examined and fleas were evaluated to be dead, alive or moribund on 2, 4, 8, 12, and 24 hours post treatment. All alive and moribund fleas were gathered and held in a separate container for 24 hours to determine mortality. Further, all fleas collected were dissected and evaluated for blood ingestion to determine if treatment prevented fleas from biting. Efficacy was calculated by subtracting the average number of fleas counted on the treated animal from the average number of fleas counted on the untreated animals divided by the average number of fleas counted on the untreated animal.

(3) **Results:**

BLOOD DETECTED IN THE BODIES OF DEAD FLEAS*
TEST DAY 0

TIME INTERVAL	TREATMENT	TOTAL NO. DEAD FLEAS RECOVERED	NO. OF FLEAS WITH BLOOD	PERCENT POSITIVE FOR BLOOD
2 HRS	ADVANTAGE	10	6	60.0
	TOP SPOT	8	6	75.0
	CONTROL	0	0	-
4 HRS	ADVANTAGE	15	15	100
	TOP SPOT	5	2	40.0
	CONTROL	3	1	33.3
8 HRS	ADVANTAGE	151	101	66.9
	TOP SPOT	165	115	69.7
	CONTROL	0	0	-
12 HRS	ADVANTAGE	99	88	88.9
	TOP SPOT	140	93	66.4
	CONTROL	1	1	100
24 HRS	ADVANTAGE	145	99	68.3
	TOP SPOT	169	153	90.5
	CONTROL	12	12	100

* DEAD FLEAS RECOVERED FROM THE DOGS DURING COMBING OR FROM PANS BENEATH THE DOGS.

BLOOD DETECTED IN THE BODIES OF LIVE FLEAS*
TEST DAY 0

TIME INTERVAL	TREATMENT	TOTAL NO. LIVE FLEAS RECOVERED	NO. OF FLEAS WITH BLOOD	PERCENT POSITIVE FOR BLOOD
2 HRS	ADVANTAGE	130	78	60.0
	TOP SPOT	116	40	34.5
	CONTROL	179	137	76.5
4 HRS	ADVANTAGE	100	85	85.0
	TOP SPOT	112	38	33.9
	CONTROL	174	122	70.1
8 HRS	ADVANTAGE	22	20	90.9
	TOP SPOT	11	7	63.6
	CONTROL	195	103	52.8
12 HRS	ADVANTAGE	0	0	-
	TOP SPOT	0	0	-
	CONTROL	177	138	78.0
24 HRS	ADVANTAGE	0	0	-
	TOP SPOT	0	0	-
	CONTROL	180	142	78.9

* LIVE FLEAS RECOVERED FROM THE DOGS DURING COMBING AND HELD FOR 24 HOURS BEFORE EXAMINATION FOR BLOOD.

LIVE FLEAS RECOVERED FROM DOGS AND PERCENT FLEA CONTROL
TEST DAY 0

TIME INTERVAL	ADVANTAGE		TOP SPOT		CONTROL	
	DOG NO.	NO. LIVE FLEAS	DOG NO.	NO. LIVE FLEAS	DOG NO.	NO. LIVE FLEAS
2 HRS	6823	57	7775	52	18175	86
	15081	73	10825	64	11631	93
	MEAN	65.0	MEAN	58.0	MEAN	89.5
	% CONTROL	27.4	% CONTROL	35.2	% CONTROL	-
4 HRS	16012	66	17206	64	HIEMBY	84
	15025	34	18604	48	15161	90
	MEAN	50.0	MEAN	56.0	MEAN	87.0
	% CONTROL	42.5	% CONTROL	35.6	% CONTROL	-
8 HRS	11698	0	18336	2	17526	98
	16744	22	BHCAVJ	9	18561	97
	MEAN	11.0	MEAN	5.5	MEAN	97.5
	% CONTROL	88.7	% CONTROL	94.3	% CONTROL	-
12 HRS	EFMGG	0	18393	0	15783	87
	2863	0	BHFMRW	0	14802	90
	MEAN	0	MEAN	0	MEAN	88.5
	% CONTROL	100	% CONTROL	100	% CONTROL	-
24 HRS	15185	0	245	0	13995	100
	15737	0	BHFMRX	0	14368	80
	MEAN	0	MEAN	0	MEAN	90.0
	% CONTROL	100	% CONTROL	100	% CONTROL	-

BLOOD DETECTED IN THE BODIES OF DEAD FLEAS*
TEST DAY 27

TIME INTERVAL	TREATMENT	TOTAL NO. DEAD FLEAS RECOVERED	NO. OF FLEAS WITH BLOOD	PERCENT POSITIVE FOR BLOOD
2 HRS	ADVANTAGE	44	40	90.9
	TOP SPOT	14	11	78.6
	CONTROL	14	12	85.7
4 HRS	ADVANTAGE	87	63	72.4
	TOP SPOT	90	65	72.2
	CONTROL	7	5	71.4
8 HRS	ADVANTAGE	67	48	71.6
	TOP SPOT	74	56	75.7
	CONTROL	12	12	100
12 HRS	ADVANTAGE	72	44	61.1
	TOP SPOT	94	54	57.4
	CONTROL	7	3	42.9
24 HRS	ADVANTAGE	87	69	79.3
	TOP SPOT	59	45	76.3
	CONTROL	10	10	100

* DEAD FLEAS RECOVERED FROM THE DOGS DURING COMBING OR FROM PANS BENEATH THE DOGS.

BLOOD DETECTED IN THE BODIES OF LIVE FLEAS*
TEST DAY 27

TIME INTERVAL	TREATMENT	TOTAL NO. LIVE FLEAS RECOVERED	NO. OF FLEAS WITH BLOOD	PERCENT POSITIVE FOR BLOOD
2 HRS	ADVANTAGE	49	40	81.6
	TOP SPOT	65	30	46.1
	CONTROL	105	105	100
4 HRS	ADVANTAGE	2	2	100
	TOP SPOT	4	4	100
	CONTROL	128	91	71.1
8 HRS	ADVANTAGE	0	0	-
	TOP SPOT	3	2	66.7
	CONTROL	128	91	71.1
12 HRS	ADVANTAGE	17	14	82.3
	TOP SPOT	6	2	33.3
	CONTROL	92	89	96.7
24 HRS	ADVANTAGE	2	2	100
	TOP SPOT	3	3	100
	CONTROL	110	69	62.7

* LIVE FLEAS RECOVERED FROM THE DOGS DURING COMBING AND HELD FOR 24 HOURS BEFORE EXAMINATION FOR BLOOD.

LIVE FLEAS RECOVERED FROM DOGS AND PERCENT FLEA CONTROL
TEST DAY 27

TIME INTERVAL	ADVANTAGE		TOP SPOT		CONTROL	
	DOG NO.	NO. LIVE FLEAS	DOG NO.	NO. LIVE FLEAS	DOG NO.	NO. LIVE FLEAS
2 HRS	6823	4	7775	35	18175	64
	15081	45	10825	30	11631	41
	MEAN	24.5	MEAN	32.5	MEAN	52.5
	% CONTROL	53.3	% CONTROL	38.1	% CONTROL	-
4 HRS	16012	0	17206	0	HIEMBY	62
	15025	2	18604	4	15161	66
	MEAN	1.0	MEAN	2.0	MEAN	64.0
	% CONTROL	98.4	% CONTROL	96.9	% CONTROL	-
8 HRS	11698	0	18336	1	17526	67
	16744	0	HHCAYJ	2	18561	61
	MEAN	0	MEAN	1.5	MEAN	64.0
	% CONTROL	100	% CONTROL	97.7	% CONTROL	-
12 HRS	EFGGG	0	18393	0	15783	54
	2863	17	HHFMRW	6	14802	38
	MEAN	8.5	MEAN	3.0	MEAN	46.0
	% CONTROL	81.5	% CONTROL	93.5	% CONTROL	-
24 HRS	15185	2	245	1	13995	49
	15737	0	HHFMRX	2	14368	61
	MEAN	1.0	MEAN	1.5	MEAN	55.0
	% CONTROL	98.2	% CONTROL	97.3	% CONTROL	-

(4) Conclusion: This study is unacceptable for the proposed study. The study supports that imidacloprid, when

applied to a dog, at 0.008 mL/kg kills fleas. Data on dogs cannot be bridged to support cat products. Further, the data do not support claims that imidacloprid prevents fleas from biting a dog.

44256902. Hopkins, T.; Woodley, I.; Gyr, P.; 1997. Imidacloprid Topical Formulation: Larvicidal Effect Against *Ctenocephalides felis* in the Surroundings of Treated Dogs.

(1) non-GLP

(2) **Methods:** This MRID consists of two studies. The first study only tested 4 dogs, while the second study tested 7 dogs in 2 groups. In order to receive meaningful statistical results from a study, the minimum number of dogs recommended to test in one group is 6. Therefore, these studies will not be considered.

(3) **Results:** As too few test animals were utilized and dogs instead of cats were utilized in these tests, the results are inapplicable to the proposed product will not help support the subject product of this review.

(4) **Conclusion:** As stated above, this MRID is **unacceptable** because of too few replicates in the study design and the use of dogs instead of cats. No claims can be supported with this test.

44256903. Cunningham, J. 1997. Evaluation of the Effects of Shampooing or Water Immersion on the Initial and Residual Efficacy of Advantage for Flea Control on Dogs.

(1) GLP

(2) **Methods:** Twenty-four adult, mix breed dogs were randomly assigned to 3 groups. On day 0, groups 1 and 2 were treated with Advantage solution (9.1% imidacloprid), per label instructions. (Dogs in group 1 received an average imidacloprid dose of 16 mg/kg, and dogs in group 2 received an average imidacloprid dose of 14.5 mg/kg). Group 3 served as the control and received a placebo treatment. Each dog was infested with 100 unfed adult fleas on days -1, 6, 13, 20, 27, and 34. Live fleas remaining on each dog were counted and removed on days 1, 7, 14, 21, 28, and 35. On day 4, group 1 dogs were shampooed with an emollient shampoo (Allegroom Virbac) and rinsed. Group 2 dogs were immersed in a tank of water for one minute. Half of group 3 dogs were shampooed and the other half were immersed in water. The water immersion treatment was repeated on the same dogs on days 11, 18, 25, and 32.

Percent control was calculated using Abbott's formula, by subtracting the average number of fleas counted on the treated animal from the average number of fleas counted on the untreated animals divided by the average number of fleas counted on the untreated animal.

(3) **Results:**

GROUP 1 - ADVANTAGE TREATMENT (DAY 0) FOLLOWED BY SHAMPOOING ON DAY 4

DOG NO.	NUMBER FLEAS / DOG						
	DAY						
	-2	1	7	14	21	28	35
202	80	0	15	17	30	17	32
315	62	0	0	1	4	1	15
353	76	0	0	0	2	1	20
369	97	0	0	0	0	0	5
401	86	0	0	3	18	11	39
497	89	0	0	1	0	0	33
523	104	0	12	35	27	19	48
526	78	0	0	0	10	13	54
TOTAL	672	0	27	57	91	62	246
MEAN	84.0	0.0	3.4	7.1	11.4	7.8	30.8
% CONTROL	-	100	96.2	92.5	88.1	92.2	65.5

GROUP 2 - ADVANTAGE TREATMENT (DAY 0) FOLLOWED BY WATER IMMERSION
ON DAYS 4, 11, 18, 25, 32

Dog No.	NUMBER FLEAS / DOG						
	DAY						
	-2	1	7	14	21	28	35
201	103	0	0	0	8	15	31
313	71	0	0	2	4	11	18
341	79	0	0	0	4	0	10
357	76	0	0	0	0	0	8
386	85	0	2	4	43	48	52
394	100	0	0	1	13	1	35
440	90	0	0	0	1	0	1
451	73	0	0	0	0	1	3
TOTAL	677	0	2	7	73	76	158
MEAN	84.6	0.0	0.3	0.9	9.1	9.5	19.8
% CONTROL	-	100	99.6	99.0	89.7	88.8	76.7

GROUP 3 - CONTROL - PLACEBO TREATMENT (DAY 0) FOLLOWED BY SHAMPOOING OR
WATER IMMERSION.

Dog No.	NUMBER FLEAS / DOG						
	DAY						
	-2	1	7	14	21	28	35
228a	69	93	101	96	89	106	91
298a	86	103	96	101	96	104	96
442a	80	78	90	80	95	93	82
450a	108	106	75	103	103	99	88
Total	343	380	362	380	383	402	357
Mean	85.8	95.0	90.5	95.0	95.8	100.5	89.3
336b	78	74	76	93	82	95	83
368b	91	55	49	88	80	86	95
371b	71	68	91	63	85	68	90
383b	84	71	90	105	105	89	103
Total	324	268	306	349	352	338	371
Mean	81.0	67.0	76.5	87.3	88.0	84.5	92.8

a - Dogs shampooed on day 4.

b - Dogs immersed in water on days 4, 11, 18, 25, 32.

(4) **Conclusion:** This study is **unacceptable** because it was tested on dogs and data on dogs cannot be used to support cat products.

IV. EXECUTIVE DATA SUMMARY:

(A) Out of the seven submitted studies, only one was rated acceptable. This acceptable study supports that imidacloprid, when applied to a cat at 10 mg/kg will kill fleas for 30 days. The study also supports that when applied at 10 mg/kg imidacloprid reduces flea eggs.

V. LABEL RECOMMENDATIONS:

(1) No changes in the Directions for Use are suggested.

(2) The following marketing claims are acceptable:

- Prevents further flea infestation for 4 weeks/1 month with just one [treatment] [application]
- This product kills fleas that may cause the incidence of a hypersensitivity skin disorder called flea allergy dermatitis (FAD)
- Kills fleas
- Kills fleas that may cause flea allergy dermatitis, flea bit anemia, and tapeworm infestation
- Stops and prevents infestation of listed pests for 4 weeks
- Flea protection
- Active against fleas
- This product is indicated for the treatment and prevention of fleas on cats
- Long lasting

(3) The following marketing claims are unacceptable:

- Kills fleas within 12 hours [of application]
- Kills reinfesting fleas within 2 hours
- Targets all life stages
- Kills flea larvae in cat's environment following contact with treated cat
- Remains effective, even after [bathing], [shampooing], water immersion or exposure to sunlight, [and]/[or] rain
- Waterproof
- Fast acting
- Flea life cycle icon/diagram
- Kills adult fleas before they lay eggs

(4) The following MRIDs should be removed from the data matrix, as they are classified as "unacceptable" to support the product: 43679503, 43679504, 43794102, 44256901, 44256902, and 44256903

(5) Note to PM/RM: the acceptable study demonstrated that the product prevents the laying of eggs, but there is not acceptable data that demonstrates the prevention of hatch or killing of eggs. This is an important distinction and should be reflected in the approved claims. Also, the product will be efficacious for 1 month. It is up to the PM to decide if "long-lasting" claims are acceptable.

These studies support that imidacloprid is effective at the minimum rate of 10mg/kg. Currently, the minimum rate of imidacloprid received based on the weight classes (see page the table on page 1 of this review) is 9.8 mg/kg. If cleared from a companion animal perspective, a shift in the weight classes would help match the minimum rate of 10 mg/kg. If this shift were to occur, the middle weight range would be 5-8 lbs and the highest weight range would be 8 lbs. plus. Again, this is reliant on approval from a companion animal review. If the companion animal reviewer decides this rate will result in harm to the animal, the 9.8 mg/kg rate, although not preferable, would be permissible.

~~CONFIDENTIAL APPENDIX - DO NOT RELEASE TO REGISTRANT~~

This product is a me-too of 11556-116 and 11556-118. As such, Sergeant's cited 7 Bayer efficacy studies (reviewed in EPA reviews dated 12/5/1995 and 5/5/1997). Although many of the MRIDs are now rated unacceptable to today's standards (see claims on page 15), the following me-too claims are allowed until the Agency calls in efficacy data for all cat products.

- Kills fleas within 12 hours
- Kills reinfesting fleas within 2 hours
- Kills adult fleas before they lay eggs, kills all life stages, and life cycle claims
- Kills fleas in 12 hours
- Waterproof
- Remains effective even after bathing, shampooing, water immersion, rain, swimming, exposure to sunlight



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEE

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

~~CONTAINS CONFIDENTIAL BUSINESS INFORMATION~~

DP BARCODE No.: D427067

FILE SYMBOL NO.: 2517-RTG

DECISION No.: 498685

PC CODE: 129099

ACTION CODE: R 315

FOOD USE: No

PRODUCT NAME: Sergeant's 9.1% Imidacloprid Spot On for Cats

DATE OUT: August 27, 2015

SUBJECT: End-Use Product Chemistry Review
Product Name: Sergeant's 9.1% Imidacloprid Spot On for Cats

FROM: Bruce F. Kitchens, Chemist
Product Chemistry Team
Chemistry, Inerts and Toxicology Assessment Branch/RD (7505P)

TO: RM 01, Venus Eagle/Rita Kumar
Invertebrate and Vertebrate Branch 3/RD (7505P)

Bruce F. Kitchens
27 Aug 2015
SRM 8/27/15

INTRODUCTION:

The registrant, Sergeant's Pet Care Products, Incorporated, is submitting an application to register the proposed end-use product, Sergeant's 9.1% Imidacloprid Spot On for Cats. The active ingredient in this product is Imidacloprid (98.0% pai) at a label nominal concentration of 9.1% a.i. This product is intended for use as an insecticide for cats. In addition, the registrant states that the proposed product is substantially similar in composition to EPA Reg. No. 11556-116 Advantage Topical Solution for Cats. In support of this request, the registrant is submitting a proposed basic and three alternate CSFs (Confidential Statements of Formula) all dated 19 Dec 2014; a draft label and product chemistry data contained in MRID#s 494692-01 through 494692-06. The Chemistry, Inerts and Toxicology Assessment Branch (CITAB) has been asked to review this submission.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient: Imidacloprid (9.10% ai)

Formulation Type: RTU

2. Has the registrant claimed substantial similarity to a registered product?

[X] Yes; [] No; [] NA; if yes give the registration number of the cited product.

EPA Reg. No. 11556-116

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3. All of the source materials of the active ingredient are derived from registered sources- ☒ Yes ☐ No

4. All inert ingredients have been screened by IIAB and are approved for the proposed labeled uses.

5. Confidential Statement of Formula:

☒ Basic - Dated: 19 Dec 2014

Resubmitted Dated:

☒ Alternate (1,2,3) - Dated: 19 Dec 2014

Resubmitted Dated:

Alternate CSF complies with 40 CFR 152.43

☒ Yes ☐ No ☐ NA

6. Product label

a. Ingredient statement: Nominal concentration of AI listed on CSF concurs with product label (PR Notice 91-2).

☒ Yes, if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)

☒ Yes; ☐ No; if not, explain below

Metallic equivalent: ☐ Yes ☒ NA

Soluble arsenic: ☐ Yes ☒ NA

Isomeric ratios: ☐ Yes ☒ NA

Acid Equivalent: ☐ Yes ☒ NA

b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes; ☐ No; ☒ NA

Methanol at > 4%: ☐ Yes; ☐ No; ☒ NA

Sodium nitrate/sodium nitrite ☐ Yes; ☐ No; ☒ NA

c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☐ Yes ☒ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes; ☐ No; ☒ NA; if not, explain below

d. Label requires an additional Storage and Disposal statement: ☐ Yes ☒ No; if yes explain below:

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FOOD USE: No

PRODUCT NAME: Sergeant's 9.1% Imidacloprid Spot On for Cats

7. Group A: Product Chemistry Data

CITAB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		CITAB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	494692-01
830.1600	Description of materials used to produce the product		X		A	494692-01
830.1650	Description of formulation process		X		A	494692-01
830.1670	Discussion on the formation of impurities		X		A	494692-01
830.1700	Preliminary analysis			X	NA	
830.1750	Certified limits (158.350)	Standard certified limits	X			see basic csf 12/19/14
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		X		A	494692-02

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable.

8. Group B:

Guideline No.	Study Title	Value or Qualitative Description	CITAB's Assessment of Data	MRID Nos.
830.6303	Physical State	Yellow liquid with an odor characteristic of organic solvents	A	494692-03 494692-04
830.6314	Oxidation/ Reduction	Product not expected to be oxidized or reduced based on chemical structures of the components.	A	494692-03
830.6315	Flammability	98.5°C	A	494692-03 494692-06
830.6316	Explosibility	Product does not contain explosive components.	NA	
830.6317	Storage stability	Active ingredient content remained stable when stored in glass bottles at 54°C for 14-days. Active ingredient content increased slightly when stored in PE tubes at 54°C for 14-days.	A	494692-05
830.6320	Corrosion Characteristics	No signs of damage or corrosion observed after 14-days storage at 54°C.	A	494692-05
830.7000	pH	Product is not dispersible with water.	NA	
830.7100	Viscosity	6.60 MPas at 20°C	A	494692-03, 494692-04
830.7300	Density (units)	1.099 g/cm ³ at 20°C	A	494692-03 494692-04

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress;
U = Upgradeable.

DP BARCODE No.: D427067

PC CODE: 129099

FOOD USE: No

FILE SYMBOL NO.: 2517-RTG

ACTION CODE: R 315

PRODUCT NAME: Sergeant's 9.1% Imidacloprid Spot On for Cats

DECISION No.: 498685

CONCLUSIONS:

CITAB has reviewed the product chemistry data submitted for the proposed end-use product and has concluded that:

1. The basic formula CSF for the proposed end-use product, Sergeant's 9.1% Imidacloprid Spot On for Cats dated 19 Dec 2014 is acceptable.

The proposed alternate formula CSFs (alt. 1-3) for the end-use product, Sergeant's 9.1% Imidacloprid Spot On for Cats all dated 19 Dec 2104 are acceptable.

2. This submission satisfies the data requirements as specified in 40 CFR 158.320, 158.325, 158.335, 158.340, 158.350, and 158.355 with respect to product identity and composition, description of materials used to produce the product, description of formulation process, discussion of formation of impurities, certified limits, and enforcement analytical method.
3. This submission satisfies the data requirements as specified in 40 CFR 158.310 with respect to physical and chemical properties.
4. The proposed product has been determined to be substantially similar in composition to EPA Reg. No. 11556-116 Advantage Topical Solution for Cats.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

October 7, 2015

MEMORANDUM

Subject: Name of Pesticide Product: SERGEANT'S® IMIDACLOPRID SPOT
ON FOR CATS
EPA Reg. No. /File Symbol: 2517-RTG
DP Barcode: DP 427070
Decision No.: 498685
Action Code: R315
Submission#: 962065
E-Sub#: 7015
PC Code: 129099 (Imidacloprid: 9.1%)

From: Byron T. Backus, Ph.D., Toxicologist *Byron T. Backus*
CITAB *Oct - 7 - 2015*
Registration Division (7505P) *SKR*

Through: John Redden, M.S., Senior Risk Assessor
CITAB
Registration Division (7505P)

To: Rita Kumar/Venus Eagle RM 01
IVB3
Registration Division (7505P)

Registrant: SERGEANT'S PET CARE PRODUCTS, INC.
10077 South 134th St.
Omaha, NE 68138-3710

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>by wt.</u>
129099 Imidacloprid	9.10%
<u>Other Ingredient(s):</u>	<u>90.90%</u>
TOTAL	100.00%

ACTION REQUESTED: "Please provide a...full review of...this me-too (11556-116 and -118) application for a cat spot-on product. All companion animal studies are cited. This is an e-

submission and all the information – cover letter, CSFs, label and data matrix – are in Documentum. Copies of the cover letter and proposed label are also enclosed here...”

COMMENTS AND RECOMMENDATIONS:

1. The proposed dosage levels are 0.4 mL for cats weighing 2 to 9 lbs (with the stipulation that this product is not to be applied to cats weighing less than 2 lbs); and 0.8 mL for cats weighing more than 9 lbs. From the CSF the density is 1.099 g/cm³ so a dosage level of 0.4 mL on a 2 lb (0.9072 kg) cat would be a dosage of 44.1 mg imidacloprid/kg; and a dosage of 0.8 mL on a 9 lb (4.082 kg) cat would be a dosage of 19.6 mg imidacloprid/kg.
2. The registrant has cited (data matrix dated December 19, 2014) the following MRIDs to satisfy the companion animal safety study requirements: 43679501, 43679502, 44157301, 44157302, and 44179802.
3. The studies in MRID 43679501 and 43679502 were reviewed by HED (TXR 0011821; memorandum from Myron S. Ottley dated March 5, 1996) with the following comments:

[For 43679501]: “a total of 4 males and 5 females in 3 groups (1-2/sex/group) were dermally exposed to Imidacloprid, 10% Spot-On formulation. Dose levels were 50 mg/kg/day x 1 day, and 50/mg/kg/day x 3 days. Controls received placebo (Formulation less active ingredient) at 50/mg/kg/day x 3 days. Animals then were observed for 14 days.

“No major treatment related dermal, clinical signs, body weight effects or clinical chemistry changes were observed. Necropsy was not done due to lack of toxicosis. The study demonstrates that cats can tolerate 50 mg/kg without significant adverse reactions.

“This acute dermal study is classified as Acceptable when combined with another study (see below). The number of animals/group is too small and not in keeping with general study practice. However, when data are combined with the companion study in the cat (MRID 43679502), the information is considered useful. This satisfies the requirements for a domestic animal study in the cat.”

[For 43679502]: “18 cats of various and mixed breed (3 or 4 males, 2 or 3 females per group of which 1 or 2 males/group and 1 or 2 females/group were 11 - 12 weeks old) were dermally exposed to Imidacloprid, 10% Spot-On at seven-day intervals for a total of eight treatments. Dose levels were 10 or 50 mg/kg. Controls received placebo (formulation less active ingredient) at 50/mg/kg.

“No major treatment related dermal, clinical signs, body weight effects or clinical chemistry/hematology were observed. Necropsy was not done due to lack of toxicosis. The study demonstrates that adult cats can tolerate up to 50 mg/kg of the active ingredient without significant reactions.

“This repeated dose dermal study satisfies the requirement for a Domestic Animal Safety study for topical use in adult cats and is classified as Acceptable.”

It was the conclusion of the original reviewer that these two studies indicate adult cats can tolerate up to 50 mg/kg of the active ingredient, so they would (applying a 5X safety factor) support a dosage rate of 10 mg imidacloprid/kg. These studies then do not support the

proposed maximum dosage rates for 2517-RTG (0.4 mL on a 2 lb cat = 44.1 mg imidacloprid/kg; 0.8 mL on a 9 lb cat = 19.6 mg imidacloprid/kg).

4. The study in MRID 44157301 [Shmidl, J.; Arther, R. (1996) General Safety Evaluation for Topical Use of Imidacloprid (Advantage) Spot-On on Six Week Old Kittens: Lab Project Number: 74746: TR-96F-004: 10332. Unpublished study prepared by Bayer Corp., DeSoto Research Facility. 41 p. Relates to L0000102] was reviewed by HED (TXR 0012322, memorandum from Virginia Dobozy dated September 24, 1997]. The following is from the executive summary:

“In a domestic animal safety study (MRID # 44157301), six 6 week-old kittens/sex were treated with Advantage™ (9.1% imidacloprid) at 5X the recommended use rate (2.0 ml). Six kittens/sex were also treated with the vehicle control at the recommended use rate (0.4 ml). According to the study protocol, the animals were supposed to receive 8 treatments at weekly intervals. However, two males and two females in the imidacloprid-treated group died or were euthanized within 72 hours after the first treatment. On necropsy, the two females had suppurative cholangiohepatitis which was assumed to be due to an ascending bacterial infection in the liver. In addition, one female had mild diffuse hepatic lipidosis. There were no remarkable findings in the males... The study report concluded that the kittens were stressed from weaning and were not able to tolerate 5X the recommended use rate.

“The study is considered unacceptable and cannot be upgraded. It was terminated prior to completion due to animal welfare considerations.”

5. The study in MRID 44157302 [Shmidl, J.; Arther, R. (1996) General Safety Evaluation for Topical Use of Imidacloprid (Advantage) Spot-On on Kittens Eight Weeks of Age: Lab Project Number: 74747: TR-96F-006: 10332. Unpublished study prepared by Bayer Corp., DeSoto Research Facility. 45 p. Relates to L0000102.] was reviewed by HED (TXR 0012322, memorandum from Virginia Dobozy dated September 24, 1997). The following is from the executive summary:

In a domestic animal safety study (MRID # 44157302), six 8 week-old kittens/sex were treated with Advantage™ (9.1% imidacloprid) at 5X the recommended use rate (2.0 ml) at weekly intervals for eight treatments. Six kittens/sex were treated with the vehicle control at the recommended use rate (0.4 ml) at weekly intervals for eight treatments. There was no evidence of treatment-related toxicity in clinical signs or clinical pathology parameters. All animals gained weight during the study. It was demonstrated that 8 week-old kittens can tolerate a dose of 5X the recommended use rate.

The study is considered acceptable and satisfies the draft guideline requirements (81-6) for a domestic animal safety study.

The initial body weights of the twelve 5X kittens are reported on page 8 of MRID 44157302; the 4 lowest weight males (0.73, 0.73, 0.83 and 0.84 kg) and 4 lowest weight females (0.82, 0.82, 0.85, 0.85 kg) had a mean weight of 0.81 kg. Since each was treated with 2.0 mL of a formulation containing 9.1% imidacloprid, they were each exposed to 207 mg imidacloprid which, divided by 0.81 kg, results in a mean of 256 mg/kg ($207 \text{ mg} \div 0.81 \text{ kg}$). **This study supports a dose rate of $256 \text{ mg/kg} \div 5 = 51.1 \text{ mg/kg}$, which is greater than (and supports) the proposed maximum dosage rates for 2517-RTG (0.4 mL on a 2 lb cat = 44.1 mg imidacloprid/kg; 0.8 mL on a 9 lb cat = 19.6 mg imidacloprid/kg).**

6. The study in MRID 44179802 [Shmidl, J.; Arther, R. (1996) Acute Oral Toxicity Evaluation of Imidacloprid (Advantage) in Cats: Lab Project Number: TR-96F-011: 74769: J:\USERS\LINDA\NOREPORT\JAS0173.RPT. Unpublished study prepared by Bayer Corp., Animal Health. 10 p.]. This was not a companion animal safety study, but an acute oral study. Six cats received a placebo formulation (formulation less the active ingredient), while the remaining six (2M and 4F; weights ranging from 5.8 to 8.6 lbs) were orally dosed with 0.4 mL of a 9.1% imidacloprid-containing formulation. 3/6 cats receiving the imidacloprid formulation vomited on the day of administration, and one of these cats also vomited on day 3. While providing useful information, this study does not satisfy the 870.7200 guideline requirements.
7. CITAB concludes that the citation to MRID 44157302 satisfies the companion animal safety data requirements (including minimum age of 8 weeks and the proposed maximum dosage rates of 0.4 mL on a 2 lb cat = 44.1 mg imidacloprid/kg; 0.8 mL on a 9 lb cat = 19.6 mg imidacloprid/kg) to support the registration of 2517-RTG.

Kumar, Rita

From: Marchese, Jacquelyn
Sent: Thursday, May 28, 2015 10:25 AM
To: Kumar, Rita
Subject: 2517-RTG, 2517-RTU Pass Technical Screen

Hi Rita,

2517-RTG and 2517-RTU pass the efficacy technical screen. Let me know if you have any questions.

Thanks,
Jackie

Jacquelyn Marchese
Entomologist
OCSPP/OPP/RD/IVB3
Email: Marchese.Jacquelyn@epa.gov
Phone: (703) 347-0559

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

SIMILARITY CLINIC MEMORANDUM:

Subject: EPA Reg. No.: 2517-RTG/9.1% Imidacloprid Spot On for Cats
DP Barcode: 425147
PC Code: 129099

From: Marianne Lewis, Biologist
Insecticides/Rodenticides Branch
Registration Division (7505P)

To: Venus Eagle, PM 01
Invertebrate/Vertebrate Branch 3
Registration Division (7505P)

Applicant: Sergeant's Pet Care Products, Inc
10077 South 134th Street
Omaha, NE 68138-3710

Marianne Lewis
scr 1/21/15

FORMULATION FROM EPA Reg. No. 2517-RTG LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Imidacloprid:	9.1%
<u>Inert Ingredient(s):</u>	90.9%
Total	100.0%

BACKGROUND: The registrant is claiming substantial-similarity to EPA Reg. No. 11556-116 and is citing specific MRID's to support the registration of their new product, EPA Reg. No. 2517-RTG. The MRID's are as follows: 436796-01 (81-1), 436796-02 (81-2), 436796-03 (81-3), 436796-04 (81-4) 436796-05 (81-5) and 436796-06 (81-6).

After comparing the CSF from the subject product and the CSF from the test material used in the studies, the EPA will be allow the registrant to cite the studies listed above for the subject product. The following acute toxicity categories will be assigned to the subject product: acute oral (81-1) – III; acute dermal (81-2) – III; acute inhalation (81-3) – IV; primary eye irritation (81-4) – II; primary skin irritation (81-5) – IV; and will be classified as a non sensitizer (81-6).

RECOMMENDATIONS:

- The subject product will be assigned the Toxicity Categories listed above.
- The subject product will be classified as a non sensitizer.

The acute toxicity profile for EPA Reg. No. 2517-RTG is currently:

Acute Oral	III
Acute Dermal	III
Acute Inhalation	IV
Primary Eye	II
Primary Dermal	IV
Skin sensitization	non sensitizer

NOTE: The acute toxicity requirements have been satisfied for the subject product.

LABELING:

ID #: 002517-RTG

**SERGEANTS 9.1% IMIDACLOPRID SPOT
ON FOR CATS**

CHILD RESISTANT PACKAGING REQUIRED:

Based on primary eye irritation Toxicity Category II – residential use

SIGNAL WORD: WARNING AVISO

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

Causes substantial but temporary eye injury. Harmful if swallowed. Harmful if absorbed through skin. Do not get in eyes or on clothing. Avoid contact with skin. Wear protective eyewear (goggles, safety glasses, face shield), long sleeved shirt, long pants, shoes, socks and chemical resistant gloves (barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride, or viton, selection category C).

FIRST AID:

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

USER SAFETY RECOMMENDATIONS:

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Note to CRM/PM/Registrant:

The proposed label should contain a Note to Physician which addresses the primary eye irritation Toxicity Category II. The following statements are some suggested types of information that could be included, if applicable, in the Note to Physicians:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

comp animal screen



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

May 11, 2015

MEMORANDUM:

Subject: Name of Pesticide Product: SERGEANT'S 9.1% IMIDACLOPRID SPOT ON FOR CATS
EPA Reg. No. /File Symbol: 2517-RTG
DP Barcode: DP 427070 (screen review)
Decision No.: 498685
Action Code: R315
PC Codes: 129099 (Imidacloprid: 9.1%)

From: Byron T. Backus, Ph.D., Toxicologist
IVB1
Registration Division (7505P)

To: Rita Kumar RM 01
IVB3
Registration Division (7505P)

Registrant: SERGEANT'S PET CARE PRODUCTS, INC.

Byron T. Backus
May 11, 2015
Eugenia McAndrew

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>by wt.</u>
129099 Imidacloprid	9.1%
<u>Other Ingredients:</u>	90.9%
TOTAL	100.0%

ACTION REQUESTED: "Please provide a technical screen and full review of this me-too (11556-116 and -118) application for a cat spot-on product..."

COMMENTS AND RECOMMENDATIONS:

1. The registrant is citing MRIDs 43679501, 43679502, 44157301, 44157302, 44179802 and 44179802 to satisfy the companion animal (cat and kitten) safety study data requirements for the registration of 2517-RTG.
2. After a search in OPPIN query, it is concluded that these citations are sufficient to allow a full review to determine whether the companion animal safety data requirements for the registration of 2517-RTG have been satisfied and if the proposed dosages, minimum age and minimum weight are supported.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: D427067; **FILE SYMBOL No.:** 2517-RTG (screen); **PRODUCT NAME:** Sergeant's 9.1% Imidacloprid Spot On for Cats; **DECISION No.:** 498685; **PC Code(s):** 129099; **ACTION CODE:** R315; **FOOD Use:** No

DATE OUT: May 8, 2015

SUBJECT: Completeness check screening for end use product "Sergeant's 9.1% Imidacloprid Spot On for Cats"

FROM: Shyam Mathur,
Product Chemistry Team Leader
CITAB / RD (7505P)

TO: Rita Kumar / Venus Eagle, RM 01
I-V Branch 3 / RD (7505P)

Company Name: Sergeant's Pet care products Incorporation
Formulation Type: Insecticide
Active Ingredient(s): Imidacloprid (9.1%)
MRID No(s): 49469201 to 49469206

CONCLUSION:

Deficiencies: No

(if there are deficiencies they are indicated below each heading as Note 1, Note 2 Etc)

Group A: All required data submitted

Group B: All required data submitted

CSF: Basic CSF (dated 12-19-2015) has been submitted. According to the registrant, they will submit a revised basic CSF soon.

Product label: Yes

Note to PM: If the deficiencies are found in the screen results, please inform the registrant and bring back to the author of this report or to Joe the corrected deficiencies in response to 10 day letter, so that it can be attached to the original bean, if the data package is still in TRB. New Bean is required in case the bean has been closed by TRB. Thank you.

Kumar, Rita

From: Mary Hunt <mhunt@exponent.com>
Sent: Tuesday, April 28, 2015 11:58 AM
To: Kumar, Rita
Cc: Kelly Hoskins; Eagle, Venus; Stephanie Sarraino
Subject: RE: Sergeant's pet product applications
Attachments: Transmittal for Dog Submission.pdf

Hi, Rita,

Thank you for the email. I don't know if it is helpful to you, but these were submitted electronically, and my understanding was that a transmittal was submitted. That being said, please see the attached transmittal and note that all data was submitted under the 2517-RTU imidacloprid dog spot on. Please let me know if you need any other information or further clarification.

Thanks, again,
Mary

From: Kumar, Rita [mailto:Kumar.Rita@epa.gov]
Sent: Tuesday, April 28, 2015 11:46 AM
To: Mary Hunt
Cc: Kelly Hoskins; Eagle, Venus
Subject: Sergeant's pet product applications
Importance: High

Hi Mary: I am doing a preliminary review of these applications. I noticed that there is no transmittal document. Can you please clarify what new data you are submitting to support these four cat and dog products, esp. what is being done for product chemistry. A transmittal document is helpful for us to know what new data are submitted, and we can assume that rest of the data in data matrix are cited.

Regards,
Rita

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-3710

CONTACT PERSON (Return to)

James Messina
Exponent, Inc.
1150 Connecticut Ave. NW, Suite 1100
Washington, DC 20036

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

This submission is prepared to support an EPA registration application for the new "me-too" end-use product, Sergeant's 9.1% Imidacloprid Squeeze On for Dogs.

SUBMITTAL DATE:

December 19, 2014

Volume	Study Title	MRID No.
1	Administrative Materials	49469200
2	Group A Product Chemistry for Sergeant's 9.1% Imidacloprid Spot-on Products	49469201
3	Analytical Method for Sergeant's 9.1% Imidacloprid Spot-On Products	49469202
4	Summary of Group B Product Chemistry and Waivers for Sergeant's 9.1% Imidacloprid Spot-on Products	49469203
5	Physical and Chemical Characteristics: Color, Viscosity, and Density for Sergeant's 9.1% Imidacloprid Spot-on Products	49469204
6	Accelerated 14-Day Storage Stability and Corrosion Characteristics of Sergeant's 9.1% Imidacloprid Spot-on Products	49469205
7	Flashpoint for Sergeant's 9.1% Imidacloprid and 9.1% Imidacloprid + 0.46% Pyriproxyfen Spot-on Products	49469206



Sergeant's Pet Care Products, Inc.

10077 South 134th Street • Omaha, NE 68138- 3710 • Telephone 402.938.7000 • Fax 402.938.7091 • www.sergeants.com

April 20, 2015

Venus Eagle, PM 1
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Dear Ms. Eagle:

Sergeant's Pet Care Products, Inc. (EPA Company Number 2517), authorizes Exponent, Inc. (1150 Connecticut Avenue, NW, Suite 1100, Washington DC, 20036) to act on our behalf, as an Authorized Representative, for all necessary interactions regarding our product registration applications and registrations. Please note that this does not change the current filed Authorized Agent for Sergeant's Pet Care Products, Inc.

The Exponent, Inc. contacts include as follows:

Jim Messina and/or Mary M. Hunt and/or Reg Coler
Exponent, Inc.
1150 Connecticut Ave., NW
Suite 1100
Washington, DC 20036
(202) 772-4932 / (202) 549-9761 / (202) 772-4965
(202) 772-4979 fax
jmessina@exponent.com / mhunt@exponent.com / rcoler@exponent.com

If you have any questions, please contact me at (402) 938-7079 or khoskins@sergeants.com.

Sincerely,

Kelly R. Hoskins
Manager of Regulatory Affairs

cc: Jim Messina, Exponent, Inc.

Kumar, Rita

From: Mary Hunt <mhunt@exponent.com>
Sent: Friday, April 03, 2015 5:18 PM
To: Kumar, Rita
Cc: Eagle, Venus
Subject: FW: New registration applications for imidacloprid
Attachments: Letter of Authorization Dec 09.pdf

Hi, Rita,

Please see the attached Sergeant's letter, authorizing Exponent as representative.

Please let me know if you have any questions, regarding the file jackets: 2517-RTG, 2517-RTU, 2517-RTA, and 2517-RTL (please email chain below).

Thank you,
Mary

Mary McKinney Hunt
Managing Regulatory Consultant
E^xponent[®], Inc
1150 Connecticut Avenue, Suite 1100 | Washington, DC 20036 |
p: 202.549.9761 | e-mail: mhunt@exponent.com | web: www.exponent.com

From: Kelly Hoskins [<mailto:Kelly.Hoskins@perrigo.com>]
Sent: Thursday, April 02, 2015 5:15 PM
To: Kumar, Rita; Mary Hunt
Cc: Eagle, Venus; James Messina
Subject: RE: New registration applications for imidacloprid

Rita,
Yes Exponent is an Agent of Sergeant's and has been on file for years, we will get you the necessary documents.

Kelly Hoskins | Regulatory Affairs
Sergeant's Pet Care Products, Inc.
A Perrigo Company
10077 South 134th Street
Omaha, NE 68138-3710
T: 402.938.7079
F: 402.938.7179
E: khoskins@sergeants.com | sergeants.com

Sergeant's
A Perrigo Company

From: Kumar, Rita [<mailto:Kumar.Rita@epa.gov>]
Sent: Thursday, April 02, 2015 3:50 PM
To: Kelly Hoskins
Cc: Eagle, Venus
Subject: New registration applications for imidacloprid

Hi Kelly: I have just started the preliminary review of the following four pet spot-on or squeeze-on applications from Sergeants:

2517-RTG
2517-RTU
2517-RTA
2517-RTL

In the jackets for these, I have seen correspondence with Mary Hunt of Exponent, but did not find an authorization letter from Sergeants assigning Exponent (Mary Hunt) as the designated agent. Can you please send me a letter of authorization to this effect, and also advise if I should just communicate with mary, or you, or both regarding these applications? Thanks.

Best Regards,
Rita

NOTICE: This e-mail message and any attachments are confidential and intended solely for use of the intended recipient. If you are not the intended recipient, you should not review, retransmit, convert to hard copy, copy, use or disseminate this e-mail or any attachments to it. If you have received this e-mail in error, please immediately notify us by return e-mail and delete this message and any attachments from your computer system. Please note that if this e-mail message contains a forwarded message or is a reply to a prior message, some or all of the contents of this message or any attachments may not have been produced by the sender. This notice is automatically appended to each e-mail message leaving the senders e-mail domain. Thank you.

Kumar, Rita

From: Kumar, Rita
Sent: Thursday, April 02, 2015 4:50 PM
To: KHoskins@SERGEANTS.com
Cc: Eagle, Venus
Subject: New registration applications for imidacloprid

Hi Kelly: I have just started the preliminary review of the following four pet spot-on or squeeze-on applications from Sergeants:

2517-RTG
2517-RTU
2517-RTA
2517-RTL

In the jackets for these, I have seen correspondence with Mary Hunt of Exponent, but did not find an authorization letter from Sergeants assigning Exponent (Mary Hunt) as the designated agent. Can you please send me a letter of authorization to this effect, and also advise if I should just communicate with mary, or you, or both regarding these applications? Thanks.

Best Regards,
Rita

Hill, Shaunta

From: Mary Hunt <mhunt@exponent.com>
Sent: Tuesday, March 03, 2015 3:19 PM
To: Hill, Shaunta
Subject: pending EPA Reg. 2517-RTG.& 2517-RTU
Attachments: 2517-RTG Revised Label 3-2-15.pdf; 2517-RTU Revised Label_3-2-15.pdf

Hi, Shaunta,

Per our discussions regarding the two pending applications for new pesticide products, please see the attached revised documents for Sergeant's 9.1% Imidacloprid Spot On for Cats (2517-RTG), and Sergeant's 9.1% Imidacloprid Squeeze On for Dogs (2517-RTU). I understand that you will forward these documents to the PM, Venus Eagle.

You may recall, these actions were required by the Agency to be changed from a PRIA3 category R301 to category R315.

Note that the Master label has been revised to reduce [brackets] in efficacy claims to make the statements clearer. After a review of the data matrices for these products, it appears no revised EPA form 8570-34 Certification with Respect to Citation of Data is required.

Please do not hesitate to call me if you have any questions or need further clarification.

Thank you,
Mary

Mary McKinney Hunt

Managing Regulatory Consultant

Exponent[®], Inc

1150 Connecticut Avenue, Suite 1100 | Washington, DC 20036 |

p: 202.549.9761 | e-mail: mhunt@exponent.com | web: www.exponent.com

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Recd. 3/24/15

Sergeant's® Master Label

02 March 2015

Version 15.1

EPA Reg. No. 2517-RTG

Information in { } is optional.

Information in { } is note to reviewer.

Page 1 of 9

FRONT PANEL

Cats Spot On Imidacloprid

[Optional text appears in brackets/parenthesis – the final label may include some or all of the optional text on front, back or side label panels]

Sergeant's® 9.1% Imidacloprid Spot On for Cats

{One of the following statements will appear on appropriate weight band market label front panel as required per Agency's pet spot-on mitigation measures:}

For use ONLY on cats [[&][and] kittens] [weighing] 2 [-][to] 9 lbs. and over 8 weeks [old][of age]

For use ONLY on cats [[&][and] kittens] [weighing] 2 [-][to] 9 lbs. and 8 weeks [of age] or older

For use ONLY on cats [[&][and] kittens] [weighing] [more than][over][>] 9 lbs. and over 8 weeks [old][of age]

For use ONLY on cats [[&][and] kittens] [weighing] [more than][over][>] 9 lbs. and 8 weeks [of age] or older

ONLY for cats [[&][and] kittens] over 8 weeks [old][of age] and [weighing] 2 [-][to] 9 lbs.

ONLY for cats [[&][and] kittens] 8 weeks [of age] or older and [weighing] 2 [-][to] 9 lbs.

ONLY for cats [[&][and] kittens] over 8 weeks [old][of age] and [weighing] [more than][over][>] 9 lbs.

ONLY for cats [[&][and] kittens] 8 weeks [of age] or older and [weighing] [more than][over][>] 9 lbs.

ACTIVE INGREDIENT:

Imidacloprid.....9.10%

OTHER INGREDIENTS:90.90%

[TOTAL]100.00%

KEEP OUT OF REACH OF CHILDREN WARNING

[See [Back][or][Side][Label[s][Panel[s]] for Additional Precautionary Statements]

NET CONTENT: X fl oz [Y – X fl oz applicators]

[0.014 fl oz (0.4 mL) [tubes][vials][applicators][pipettes]]

[0.027 fl oz (0.8 mL) [tubes][vials][applicators][pipettes]]

[ABNs]

[SENTRY® Vet for Cats Imidacloprid]

[SENTRY® Vet Advanced Flea for Cats]

[SENTRY® Vet FleaGuard for Cats]

[SENTRY® Vet Vantage for Cats]

[SENTRY® Vet Flea Vantage for Cats]

[SENTRY® Advanced for Cats Imidacloprid]

[SENTRY® Advanced FleaGuard for Cats]

[SENTRY® Advanced Vantage for Cats]

[SENTRY® Advanced Flea Vantage for Cats]

Sergeant's® Master Label

02 March 2015

Version 15.1

EPA Reg. No. 2517-RTG

Information in [] is optional.

Information in { } is note to reviewer.

Page 2 of 9

[SENTRY® Advanced VetSpot for Cats]
[PetArmor® Vantage for Cats]
[PetArmor® Advant for Cats]
[PetArmor® FleaGuard for Cats]
[PetArmor® Advanced for Cats]
[PetArmor® Flea Vantage for Cats]
[PetArmor® Adv Flea for Cats]
[PetArmor® Adv.Flea for Cats]
[PetArmor® AdVet for Cats]

[Active Ingredient Reference Statements]

[Contains imidacloprid, [the] [same] active ingredient used in
{OR}

[Compare to the active ingredient in
{OR}

[Contains [the] [same] active ingredient used in
{OR}

[[Brand Name] [This product] contains imidacloprid, [the] [same] active ingredient used in
{OR}

[[Brand Name] [This product] contains imidacloprid, compared to [the] [same] active
ingredient used in

*[Advantage® 9 Topical Solution] [Advantage® for Small Cats] [DefenseCare Flea Protection
Small Cat] [Advantage® TM 9 (Imidacloprid) Topical Solution].*]*

*[Contains imidacloprid, [the] [same] active ingredient used in [Advantage® 18 Topical
Solution] [Advantage® for Large Cats] [DefenseCare Flea Protection Large Cat] [DefenseCare
Flea Protection Large Cats] [Advantage® 18 (Imidacloprid) Topical Solution].*

**)*

[[*][Brand Name][This product] is not manufactured or distributed by Bayer Healthcare
LLC, the makers of

*[Advantage® 9 Topical Solution] [Advantage® for Small Cats] [DefenseCare Flea Protection
Small Cat] [Advantage® TM 9 (Imidacloprid) Topical Solution].*]*

*[Contains imidacloprid, [the] [same] active ingredient used in [Advantage® 18 Topical
Solution] [Advantage® for Large Cats] [DefenseCare Flea Protection Large Cat] [DefenseCare
Flea Protection Large Cats] [Advantage® 18 (Imidacloprid) Topical Solution].*]*

[Compare to

*[Advantage® 9 Topical Solution] [Advantage® for Small Cats] [DefenseCare Flea Protection
Small Cat] [Advantage® TM 9 (Imidacloprid) Topical Solution],*

*[Contains imidacloprid, [the] [same] active ingredient used in [Advantage® 18 Topical
Solution] [Advantage® for Large Cats] [DefenseCare Flea Protection Large Cat] [DefenseCare
Flea Protection Large Cats] [Advantage® 18 (Imidacloprid) Topical Solution],*

contains the same active ingredient].]*

Sergeant's® Master Label

02 March 2015

Version 15.1

EPA Reg. No. 2517-RTG

Information in [] is optional.

Information in { } is note to reviewer.

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[[Advantage® 9 Topical Solution] [Advantage® for Small Cats] [DefenseCare Flea Protection Small Cat] [Advantage® TM 9 (Imidacloprid) Topical Solution] is a registered trademark of Bayer Healthcare LLC.]*

[[Advantage® 18 Topical Solution] [Advantage® for Large Cats] [DefenseCare Flea Protection Large Cat] [DefenseCare Flea Protection Large Cats] [Advantage® 18 (Imidacloprid) Topical Solution]*

is a registered trademark of Bayer Healthcare LLC.]

[Fleas]

[Prevents [further] flea infestation for [[four][4] weeks][1 month] with [just] one treatment]

[Prevents [further] flea infestation for [[four][4] weeks][1 month] with [just] one application]

[Brand Name] Prevents flea infestation for [four][4] weeks][1 month]

[Kills fleas within 12 hours [of application] on cats]

[Kills reinfesting fleas within 2 hours]

[Kills [adult] fleas before they lay eggs]

[[Brand Name][This product] kills fleas and may reduce the incidence of a hypersensitivity skin disorder called flea allergy dermatitis (FAD), which may be caused by the feeding activity of fleas on cats.]

[Kills flea larvae in cat's environment following contact with treated cat]

[Apply monthly [for optimal flea control]]

[Apply monthly [to control and prevent fleas]]

[Kills fleas]

[Complete Flea Protection]

[Complete Flea Control]

[Optimal Flea Control]

[Optimal Flea Protection]

[Advanced Flea Control]

[Advanced Flea Protection]

[Kill fleas in 12 hours, continues to kill for 4 weeks]

[Kills fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation]

[Kills fleas, which may be a source of flea allergy dermatitis, in 12 hours]]

[Stops and prevents infestation of listed pests for 4 weeks]

[Use [of Brand Name][of this product] kills fleas and may reduce incidence of flea bite hypersensitivity [and][or] [flea allergy dermatitis] [FAD]]

[Use [of Brand Name][of this product] kills fleas and may reduce incidence of [flea bite hypersensitivity] [and][or] flea allergy dermatitis [FAD]]

[Monthly treatment [with Brand Name][with this product] kills fleas and may reduce incidence of [flea bite hypersensitivity] [and][or] flea allergy dermatitis [FAD]]

[Monthly treatment [with Brand Name][with this product] kills fleas and may reduce incidence of flea bite hypersensitivity [and][or] [flea allergy dermatitis] [FAD]]

[Flea protection]

[Active against fleas]

[Kills fleas on [kittens and] cats]

[[Brand Name] Offers protection against fleas]

[Flea control for cats and kittens [over 8 weeks [old]][of age]]

[Flea control for cats and kittens [8 weeks [of age] or older]]

[Kills fleas within 12 hours on cats [and prevents infestations for [up to] [[4][four] weeks]][[1][one][a] month]]

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Information in [] is optional.

Information in { } is note to reviewer.

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[All Others]

[Apply to [cats and] kittens over 8 weeks old]

[Apply to [cats and] kittens 8 weeks or older]

[SENTRY®]

[PetArmor®]

[[Sergeant's] Caring For Your Pets Since 1868]

[For Cats]

[Specially Formulated for Cats and Kittens [Over 8 Weeks [Old]][of Age]]

[Specially Formulated for Cats and Kittens [8 Weeks [of Age] or Older]]

[Cats and Kittens [over 8 weeks [old]][of age]]

[Cats and Kittens [8 weeks [of age] or older]]

[Can be used on kittens [over 8 weeks [old]][of age]]

[Can be used on kittens [8 weeks [of age] or older]]

[The Only Flea Protection You Need For Your Cat[s]!]

[Original Vet Strength]

[Fast Acting] [Long Lasting]

[Convenient]

[Easy application]

[Easy to apply product]

[Easy to Use [Application]]

[One Step Hassle Free Protection!]

[Waterproof]

[Remains effective, even after [bathing,][shampooing,] water immersion, or exposure to sunlight
[and][or] [rain]]

[Remains effective, even after [bathing,][shampooing,] water immersion, or exposure to
[sunlight] [and][or] rain]

[Once a month treatment]

[Apply once every [4 weeks] [month] [30 days]!]

[4 Week Dose!] [1 Month Dose!] [30 Day Dose!]

[For year-round protection, apply [Brand Name][this product] monthly]

[Best if used year round!]

[X Applications] [4 Week Supply] [1 Month Supply]

[One Application] [8 Week Supply] [2 Month Supply]

[Two Applications] [12 Week Supply] [3 Month Supply]

[Three Applications] [16 Week Supply] [4 Month Supply]

[Four Applications] [20 Week Supply] [5 Month Supply]

[Five Applications] [24 Week Supply] [6 Month Supply]

[Six Applications] [48 Week Supply] [12 Month Supply]

[9 Applications] [52 Week Supply] [24 Month Supply]

[12 Applications] [104 Week Supply]

[24 Applications]

[[for] Small Cat[s] [2 to 9 lbs.]]

[[for] Large Cat[s] [Over 9 lbs.]]

[Direct to skin [tube][vial][applicator][pipette]]

[Easy to Use] [tube][vial][applicator][pipette]

[Clean cut [open] [tube][vial][applicator][pipette]]

[No-mess [open] [tube][vial][applicator][pipette]]

[Clip-tip design [tube][vial][applicator][pipette][!]]

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{END – FRONT PANEL}

BACK PANEL/SIDE PANEL OR INSERT

**Cats Spot On
Imidacloprid**

[The active ingredient in [Brand Name][this product] is [imidacloprid,] formulated for fast acting [and long lasting] control of fleas on cats.] [[Brand Name][This product] kills fleas within 12 hours and prevents further flea infestations for [up to] [[4][four]weeks][1][one] month][30 days].]

READ ENTIRE LABEL BEFORE EACH USE.

USE ONLY ON CATS AND KITTENS 8 WEEKS OF AGE OR OLDER.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. WARNING. Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Harmful if swallowed. Avoid contact with skin. Wash hands thoroughly with soap and warm water after handling.

HAZARDS TO DOMESTIC ANIMALS. For external use on cats only. Individual sensitivities, while rare, may occur after using ANY pesticide product for cats. Do not treat your cat with more than one pesticide product at a time. Over dosing your cat can result in serious illness and even death. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing cats.

FIRST AID	
If In Eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If Swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If on Skin or Clothing	<ul style="list-style-type: none">• Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-781-4738 for emergency medical treatment information.	
NOTE TO PHYSICIAN	
Treat the patient symptomatically.	

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR CAT, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. Do not use on animals other than cats. Do not allow your cat to ingest this product. Do not use on kittens

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under 8 weeks of age. Do not apply to cats weighing less than [2][9] lbs. Use entire contents of [tube][vial][applicator][pipette] on each cat. [Do not split one [tube][vial][applicator][pipette] between two cats.] Do not use multiple [tube][vial][applicator][pipette]s on one cat. Weigh your cat to be sure you are applying the right dose formulated for the weight of your cat. Separate the treated cat from all other cats and dogs for 24 hours after treatment has been applied.

Side Effects: Monitor your cat after application. [Some cats may experience temporary startle effects when any product is applied.] Cats may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe your cat with a mild soap and rinse with large amounts of water. If these or other side effects occur, consult your veterinarian or call 1-800-781-4738. If your cat has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your cat and continue to monitor your cat for the next 24 hours.

{OUTER PACKAGING}

How to open: Remove product [tube[s]][vial[s]][applicator[s]][pipette[s]] from the package. [Separate one [tube][vial][applicator][pipette] from the others.] Hold the [tube][vial][applicator][pipette] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply: While holding the cat with one hand, use the other hand to apply the solution. Invert the [tube][vial][applicator][pipette] and use the narrow end to part the cat's hair. Apply contents of one [tube][vial][applicator][pipette] of [Brand Name] [this product] to the cat's skin, as directed below. When finished, wrap the [tube][vial][applicator][pipette] in paper and put into the trash. Only one [tube][vial][applicator][pipette] per treatment is needed.

{For cartons containing 0.4 mL (0.014 fl oz) applicator tubes}

Only For Cats Weighing 2[-][to] 9 lbs. [Do not apply to cats weighing less than 2 lbs.] [including small cats or kittens, only 8 weeks or older] Apply one [tube][vial][applicator][pipette] 0.4 mL (0.014 fl oz [directly to skin] as a spot between the shoulder blades. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat.

{For cartons containing 0.8 mL (0.027 fl oz) applicator tube}

Only For Cats Weighing Over 9 lbs. [Do not apply to cats weighing less than 9 lbs.] Apply one [tube][vial][applicator][pipette] 0.8 mL (0.027 fl oz) [directly to skin] as a spot between the shoulder blades. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat.

FREQUENCY OF APPLICATION

[Use [Brand Name {or} this product] monthly for control of flea[s] [infestations].]
[[Studies show that] [Brand Name {or} This product] kills fleas within 12 hours of application and [lasts {or} protects] [for [up to] [[four][4] weeks][30 days][one month].]
[[Brand Name {or} This product] kills reinfesting fleas within [2][two] hours and prevents further infestations of fleas [for [up to] [[four][4] weeks][30 days][one month]].]
[If your cat is at high risk for flea reinfestation [,or in a highly infested environment], apply monthly.]

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Information in { } is note to reviewer.

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[Apply monthly for optimal flea control.]

[[Brand Name {or} This product] is waterproof and remains effective, even after water immersion or exposure to sunlight [and][or] [rain].]

[Allow treated area to dry thoroughly.]

[Do not reapply for [[four][4] weeks][30 days].]

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove [tube][vial][applicator][pipette] from pack until ready to use. Store in a cool (below 77°F/[25°C]), dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

CONTAINER DISPOSAL: **If empty:** Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[WARRANTY

Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. The directions for use of this product are believed to adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer. Sergeant's is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Sergeant's, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: [Sergeant's][SENTRY][PetArmor®] Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

[Satisfaction Guaranteed][If you are not satisfied, we will make it right with a replacement or refund.]

In Case of Emergency, call: 1-800-781-4738
Non-Emergency, call: 1-800-224-PETS (7387)

[Coupon(s) inside or on outside of box]
[Made in USA]

[Distributed by:] [Manufactured by:]
Sergeant's Pet Care Products, Inc.
Omaha, NE 68138-3710

EPA Reg. No. 2517-RTG
EPA Est. No. XXXXX-XX-XX
[BAR CODE AREA]

{END - BACK/SIDE PANEL}

{START – OPTIONAL PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT PACKAGE OR INSERT}

[How to Apply – May contain graphics illustrating product use, e.g., cat with a drop falling onto its neck from a tube/vial on front, side, or back carton label and/or applicator labeling.]

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[Clip. Part. Squeeze.]

Easier-than-ever applicator lets you *clip* the tip, *part* the fur and *apply* directly to the skin – putting proven flea protection where it needs to be.]

[Application Instructions][Directions for Use]

How to Open:

1. Remove product [tube[s]][vial[s]][applicator[s]][pipette[s]] from the package.
2. [Separate one [tube][vial][applicator][pipette] from the others.] Hold the [tube][vial][applicator][pipette] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply:

1. Invert [tube][vial][applicator][pipette] over cat and use open end to part cat's hair.
2. Apply contents of one [tube][vial][applicator][pipette] [of] [Brand Name] as a spot between the shoulder blades. Squeeze tube firmly to apply all of the solution to the cat's skin.

[Look at the Label (Look at the Label icon) [Easy] 6 Step [Easy] [Spot On] [Squeeze-On] [Topical] Checklist]

- [1] Read the label completely and follow directions
- [2] Weigh your cat
- [3] Do NOT use dog products on cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals after [treatment] [application] to avoid chance of ingestion
- [6] Do NOT split [tube][vial][applicator][pipette] between cats][and use the ENTIRE [tube][vial][applicator][pipette] contents]

[Brand Name][This product]

[Monthly reminder card]

[1][2][3][4][5][6][12][24][Month [Treatment] [Application] Tracker][Carecard]

[For year round protection apply [Brand Name][this product] monthly.]

[Cat's Name (Empty blank for owner to fill in name)]

[Cat's Weight (Empty blank for owner to fill in name)]

[First][1st] [Second][2nd] [Third][3rd] [Fourth][4th] [Fifth][5th] [Sixth][6th] [Seventh][7th]

[Eighth][8th] [Ninth][9th] [Tenth][10th] [Eleventh][11th] [Twelfth][12th]

[Dose] [Treatment] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)

[Application Date] [Date of Application]

[Calendar stickers with [Brand Name]

[Place stickers on your calendar as a reminder to reapply [Brand Name][this product] in 30 days.]

[Monthly Application Reminder Magnet (image of reminder magnet)]

[Place sticker on your calendar [or refrigerator] to remind yourself to apply [Brand Name][this product] to your cat]

[33% More Free]

[Bonus Size]

[Buy 3 get 1 free]

[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days, the reminder light will blink, reminding you to reapply [Brand Name][this product]. Press

Sergeant's® Master Label

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Information in [] is optional.

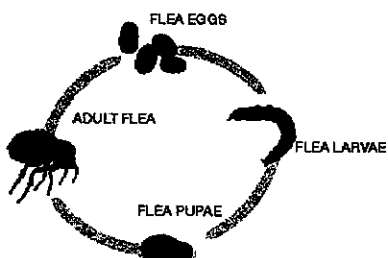
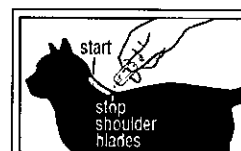
Information in { } is note to reviewer.

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the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

[Each optional graphic below may or may not appear anywhere on the finished label]

	Adult Flea	
	Fleas	
	Flea Larvae	



MADE IN THE
USA

MADE IN THE
USA
WITH GLOBAL MATERIALS

[Flea life cycle diagram] [Flea Life Cycle]

{END – OPTIONAL INSERT OR PACKAGE COPY}

TUBE/VIAL LABEL

Cats Spot On
Imidacloprid

{Front Label}

{Back Label}

[Brand Name (for Cats)] [X-Y] lbs. ≥8 wks Imidacloprid 9.10% 0.014 fl oz (or) 0.027 fl oz {label code}	KEEP OUT OF REACH OF CHILDREN WARNING: Read directions and precautions before using. Use scissors to open. EPA REG. No. 2517-RTG {label code}
--	--

{EPA REG No may be on either the front or back label}

{END – TUBE/VIAL LABEL}

Similarity Clinic Screen Completed

Date: 1/22/15

Jacket #: 2517 - RT6

Actions Done:

Acute Toxicity Review: COMPLETED → JACKET
Acute Toxicity Language for Label: DONE → REVIEW

Product Chemistry Review: CITING STUDIES →
SEND TO PC FOR
REVIEW

Transfer This Jacket To:

PMO VENUS EAGLE

Hill, Shaunta

From: Mary Hunt <mhunt@exponent.com>
Sent: Friday, February 13, 2015 3:39 PM
To: Hill, Shaunta
Subject: FW: Pay.gov Payment Confirmation: PRIA Service Fees

Hi, Shaunta,

FYI....

Thank you,
Mary

-----Original Message-----

From: notification@pay.gov [mailto:notification@pay.gov]
Sent: Friday, February 13, 2015 2:03 PM
To: Prince Bamaze
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25JPP3K6
Agency Tracking ID: 74752774031

Account Holder Name: Sergeants Pet Care Products Inc
Transaction Type: ACH Debit
Transaction Amount: \$19,892.00
Payment Date: 02/17/2015
Account Type: Business Checking
Routing Number: [REDACTED]
Account Number: *****0100

Transaction Date: 02/13/2015 03:02:50 PM EST
Total Payments Scheduled: 1
Frequency: OneTime

Registration Number: 2517-RTG; -RTU;-RTL;-RTA
Company Name: SERGEANT'S
Company Number: 2517
Action Code: R315

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

NOTICE: This e-mail message and any attachments are confidential and intended solely for use of the intended recipient. If you are not the intended recipient, you should not review, retransmit, convert to hard copy, copy, use or disseminate this e-mail or any attachments to it. If you have received this e-mail in error, please immediately notify us by return e-mail and delete this message and any attachments from your computer system. Please note that



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 13, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT
Or Pay On-Line at www.Pay.Gov (See Below for Details)

OPP Decision Number: D-498685, D-498903, D-498686 & D-498900
EPA File Symbol or Registration Numbers: 2517-RTG, 2517-RTU, 2517-RTL & 2517-RTA
Prod. Names: SERGEANT'S 9.1% IMIDACLOPRID SPOT ON FOR CATS
SERGEANT'S 9.1% IMIDACLOPRID SQUEEZE ON FOR DOGS
SERGEANT'S IMIDACLOPRID + PYRIPROXYFEN SPOT ON FOR CATS
SERGEANT'S IMIDACLOPRID + PYRIPROXYFEN SQUEEZE ON FOR DOGS
EPA Receipt Date: 19-Dec-2014
EPA Company Number: 2517
Company Name: SERGEANT'S PET CARE PRODUCTS, INC.

MS. KELLY R. HOSKINS
SERGEANT'S PET CARE PRODUCTS, INC.
PO Box 540399
OMAHA, NE 68154-0399

SUBJECT: Recoding of Four Registration Applications Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has recoded your four applications for registration that are subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

These actions has been recoded as action code R315:

NEW END-USE NON-FOOD ANIMAL PRODUCT WITH SUBMISSION OF TWO OR MORE TARGET ANIMAL SAFETY STUDIES;INCLUDES DATA AND/OR WAIVERS OF DATA FOR ONLY;;PRODUCT CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);ANIMAL SAFETY STUDIES;CHILD RESISTANT PACKAGING;

The fee for action code R315 is \$8,400. We have received payment in the amount of \$1,806 each for symbol numbers 2517-RTG and 2517-RTU and \$5,048 each for symbol numbers 2517-RTL and 2517-RTA, so please remit payment in the amount of \$19,892 for all four applications within 14 days to:

21-Day Screen Completed by
Contractor

21-Day Expires on 1-9-15

Jacket # 2517-RTG
MRID# _____

Content Screen: Recommend to Pass/Fail

11-3 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

STEPHEN SCARABLE

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 12-19-14

Experts In-Processing Signature: B.D.

Date 1-5-15

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>2517-RTG</u>		EPA Receipt Date: <u>12-19-14</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
		✓				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
		X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5					X
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
10	<u>Required Data</u> and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

Documentation: Pass

- Data Matrix issue - Preliminary Analysis guideline was not listed on the data matrix.
- Guideline is not required, per registrant,

Inerts: Pass

Inerts Approved for Non-Food Use

No Studies

Status: Pass

TW 1/16/15

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Jackson, Tracy

From: Mary Hunt <mhunt@exponent.com>
Sent: Thursday, January 15, 2015 10:02 AM
To: Jackson, Tracy
Subject: RE: Applications 2517-RTL and 2517-RTG

Tracy, I'm sorry I was not more clear; correct, these products are not TGAI.

Mary

From: Jackson, Tracy [mailto:jackson.tracy@epa.gov]
Sent: Thursday, January 15, 2015 10:00 AM
To: Mary Hunt
Subject: RE: Applications 2517-RTL and 2517-RTG

Hi Mary,

This is not a TGAI, so it would not be required, correct?

Thank You

Tracy Jackson
EPA Contractor
703-308-7227
2777 S. Crystal Drive
Arlington, VA 22202

From: Mary Hunt [mailto:mhunt@exponent.com]
Sent: Thursday, January 15, 2015 9:49 AM
To: Jackson, Tracy
Subject: RE: Applications 2517-RTL and 2517-RTG

Hi, Tracy,

Thanks for checking. Required only for a TGAI or integrated system product (which the product is not).

Hope this helps,
Mary

From: Jackson, Tracy [mailto:jackson.tracy@epa.gov]
Sent: Thursday, January 15, 2015 9:39 AM
To: Mary Hunt
Subject: RE: Applications 2517-RTL and 2517-RTG

Hello Mary,

The Preliminary analysis guideline is not required?

Thank You

Tracy Jackson
EPA Contractor
703-308-7227
2777 S. Crystal Drive
Arlington, VA 22202

From: Mary Hunt [<mailto:mhunt@exponent.com>]
Sent: Wednesday, January 14, 2015 9:16 PM
To: Jackson, Tracy
Cc: James Messina; Kelly Hoskins (Kelly.Hoskins@perrigo.com); Stephanie Sarraïno
Subject: RE: Applications 2517-RTL and 2517-RTG

Hi, Tracy,

I understand that the requirement for preliminary analysis is submitted when the product is produced by an integrated system. I do not believe that is the case for either of the pending subject products. Please let me know if you have any other questions or need further information.

Thank you for checking,
Mary

From: Kelly Hoskins [<mailto:Kelly.Hoskins@perrigo.com>]
Sent: Wednesday, January 14, 2015 6:58 PM
To: 'Jackson, Tracy'
Cc: James Messina; Mary Hunt
Subject: RE: Applications 2517-RTL and 2517-RTG

Ms Jackson,
Thank you, I will get a response to you shortly.

Kelly Hoskins | Regulatory Affairs
Sergeant's Pet Care Products, Inc.
A Perrigo Company
10077 South 134th Street
Omaha, NE 68138-3710
T: 402.938.7079
F: 402.938.7179
E: khoskins@sergeants.com | sergeants.com

Sergeant's
A Perrigo Company

From: Jackson, Tracy [<mailto:jackson.tracy@epa.gov>]
Sent: Wednesday, January 14, 2015 9:29 AM
To: Kelly Hoskins
Subject: Applications 2517-RTL and 2517-RTG

Dear Ms. Hoskins,

I am contacting you regarding your submission in support of **Sergeant's Imidacloprid + Pyriproxyfen Spot On for Cats (2517-RTL)** and **Sergeant's 9.1% Imidacloprid Spot On for Cats (2517-RTG)**. The data matrix in both submissions do not have the guideline 830.1700 –Preliminary Analysis listed. Is it required?

Thank You

Tracy Jackson
EPA Contractor
703-308-7227
2777 S. Crystal Drive
Arlington, VA 22202

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Jackson, Tracy

From: Jackson, Tracy
Sent: Wednesday, January 14, 2015 10:29 AM
To: 'khoskins@sergeants.com'
Subject: Applications 2517-RTL and 2517-RTG

Dear Ms. Hoskins,

I am contacting you regarding your submission in support of **Sergeant's Imidacloprid + Pyriproxyfen Spot On for Cats (2517-RTL) and Sergeant's 9.1% Imidacloprid Spot On for Cats (2517-RTG)**. The data matrix in both submissions do not have the guideline 830.1700 –Preliminary Analysis listed. Is it required?

Thank You

Tracy Jackson
EPA Contractor
703-308-7227
2777 S. Crystal Drive
Arlington, VA 22202



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 31, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-498685
EPA File Symbol or Registration Number: 2517-RTG
Product Name: Sergeant's 9.1% Imidacloprid Spot On for Cats
EPA Receipt Date: 19-Dec-2014
EPA Company Number: 2517
Company Name: SERGEANT'S PET CARE PRODUCTS, INC.

MS. KELLY R. HOSKINS
SERGEANT'S PET CARE PRODUCTS, INC.
PO Box 540399
OMAHA, NE 68154-0399

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R301

NEW PRODUCT;IDENTICAL OR SUBSTANTIALLY SIMILAR IN COMPOSITION AND USE TO A REGISTERED PRODUCT;REGISTERED SOURCE OF ACTIVE INGREDIENT;SELECTIVE DATA CITATION ONLY FOR DATA ON PRODUCT CHEMISTRY / ACUTE TOXICITY / PUBLIC HEALTH PEST EFFICACY, WHERE APPLICANT DOES NOT OWN ALL REQUIRED DATA NOR HAS AUTHORIZATION LETTER FROM DATA OWNER;

No additional payment is due at this time. If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "J. K. H.", written over the word "Sincerely,".

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

79
{962065+~

This package includes the following

- ☒ New Registration
- ☐ Amendment

- ☐ Studies? ☐ Fee Waiver?
- ☐ volpay % Reduction: _____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 1

Receipt No.

S-

962065

EPA File Symbol/Reg. No.

2517-RTG

Pin-Punch Date:

12/19/2014

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

R301

Granted:

R301

Amount Due: \$ 1,806.00

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: L. Roe

Date: 12/30/14

Remarks:

sim clinic

e-Submission

Receipt for Section 3

S: 962065

Milestone Email: khoskins@sergeants.com

Regulatory Type: Product Registration - Section 3



Resubmission: ☐ Yes ☒ No

Application Type: New Registration



Fee For Service: ☒ Yes ☐ No

Billable: ☒ Yes ☐ No

Company: 2517 SERGEANT'S PET CARE PRODUCTS, INC.



Print Letter

Enter More Information

Tracking

Risk Manager: Registration Division, Risk Management Team 1



Product #: 2517-RTG

Product Name: Sergeant's 9.1% Imidacloprid Spot On for Cat

Override#:

Me Too

Section3: 11556-116

Me Too Product

Name: ADVANTAGE 9 TOPICAL SOLUTION

Application Date: 19-Dec-2014



OPP Rec'd Date: 19-Dec-2014



Front End Date: 22-Dec-2014



Risk Manager Send Date:



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Receipt Content

De

CSF

Electronic Label

View/Edit

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Associated with e-Submission pkg 7015, Application for registration

New Ingredient

Request Date:

New Ingredient


Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

EPA United States Environmental Protection Agency Washington, DC 20460		<input checked="" type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide - Section I			
1. Company/Product Number 2517-NEW		2. EPA Product Manager Venus Eagle	
4. Company/Product (Name) Sergeant's Pet Care Products, Inc./Sergeant's 9.1% Imidacloprid Spot On for Cats		5. PM #1	
3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted			
5. Name and Address of Applicant (Include ZIP Code) Sergeant's Pet Care Products, Inc. 10077 South 134 th Street Omaha, NE 68138-3710 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: EPA Reg. 11556-116, -118 Nos. _____ Product Name <u>Advantage Topical Solution for Cats</u>	
Section II			
<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated XX-XX-XX <input type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated XX-XX-XX <input checked="" type="checkbox"/> "Me Too" Application <input type="checkbox"/> Other - Explain below.	
Explanation: Use additional page(s) if necessary. (For section I and Section II.)			
Sergeant's Pet Care Products, Inc. is submitting a registration application for a new me-too end-use product, Sergeant's 9.1% Imidacloprid Spot On for Cats. Sergeant's requests that the Agency review the me-too end-use product registration as a 4 month PRIA timeframe under R301.			
Section III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No *Certification must be submitted	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. 0.014 fl oz (0.4 ml) 0.027 fl oz (0.8 ml)	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per Container 1,2,3,4,5,6, 12, 24, 50, 75, 100 vials	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) Plastic Bag
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container Various	
		5. Location of Label Directions <input type="checkbox"/> On Can <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input checked="" type="checkbox"/> Other Printed box	
Section IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name James B. Messina		Title Authorized Representative	
		Telephone No. (Include Area Code) (202) 772-4932	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature BY: 		3. Title Director of Regulatory Affairs	
4. Typed Name: Kelly R. Hoskins		5. Date: December 19, 2014	

e-Submission



United States
Environmental Protection Agency
 Washington, DC 20460
Formulator's Exemption Statement
 (40 CFR 152.85)

Applicant's Name and Address Sergeant's Pet Care Products, Inc. 10077 South 134th Street Omaha, NE 68138-3710	EPA File Symbol/Registration Number 2517-NEW
	Product Name Sergeant's 9.1% Imidacloprid Spot On for Cats
	Date of Confidential Statement of Formula (EPA Form 8570-4) 12/19/2014

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Imidacloprid

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
Imidacloprid	[REDACTED]	[REDACTED]
Imidacloprid	[REDACTED]	[REDACTED]
Imidacloprid	[REDACTED]	[REDACTED]
Imidacloprid	[REDACTED]	[REDACTED]

Signature <i>Kelly R. Hoskins</i>	Name and Title Kelly R. Hoskins, Director of Regulatory Affairs	Date 12/19/2014
--------------------------------------	--	--------------------

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA
 Copy 2 - Applicant copy

e-Submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710	EPA Registration Number/File Symbol 2517-NEW
Active Ingredient(s) and/or representative test compound(s) Imidacloprid	Date 12/19/2014
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor non-food	Product Name Sergeant's 9.1% Imidacloprid Spot On for Cats

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Kelly R. Hoskins</i>	Date 12/19/2014	Typed or Printed Name and Title Kelly R. Hoskins, Director of Regulatory Affairs
--------------------------------------	--------------------	---



Sergeant's Pet Care Products, Inc.

10077 South 134th Street • Omaha, NE 68138- 3710 • Telephone 402.938.7000 • Fax 402.938.7091 • www.sergeants.com

December 19, 2014

Venus Eagle, PM1
Office of Pesticide Programs (7505P) (REGFEE)
U.S. Environmental Protection Agency
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

RE: *Submission of a "me-too" Registration Application for Sergeant's 9.1% Imidacloprid Spot On for Cats (EPA File Symbol 2517-NEW)*

Dear Ms. Eagle:

Sergeant's Pet Care Products, Inc. (Sergeants, 10077 South 134th Street, Omaha, NE 68138-3710, EPA Company Number 2517) is submitting an EPA registration application for a new end-use product containing the active ingredient imidacloprid at 9.1%. This new end-use product is substantially similar to Bayer Animal Health's EPA registered products Advantage[®] Topical Solution for Cats (EPA Reg. Nos. 11556-116 and -118). Please find enclosed the following documentation in support of the registration application for Sergeant's 9.1% Imidacloprid Spot On for Cats:

- Application for Registration (EPA Form 8750-1);
- Confidential Statement of Formula (EPA Form 8750-4);
- Formulator's Exemption Statement (EPA Form 8570-27);
- Certification with Respect to Data Citation (EPA Form 8750-34);
- Data Matrix (EPA Form 8570-35, Public and Private Versions);
- Proposed Product Label; and
- PRIA 3 Category R301 \$1,806 payment (see below for PRIA payment credits to be applied).

PRIA 3 payment credits to be applied to the Sergeant's 9.1% Imidacloprid Spot On for Cats submission:

<u>Tracking ID</u>	<u>Original Credit</u>	<u>Credit to be Applied</u>	<u>Date of Payment</u>
Pay.gov ID 25DRV9O2	\$1,900	\$1,367	01/08/2014
Pay.gov ID 25DRV3K1	\$3,798	\$439	01/08/2014

R 300 and 301

100% identical (repack): YES or NO (circle one)

{If **yes**, it's a 100% repack - then product chemistry, acute toxicity and efficacy data are not required}

Data on Group A and B must be submitted - Group A and B can not be cited.

Guideline No.	Group A: Product Chemistry Data Study Title	Data submitted	
		Yes	No
830.1550	Product Identity & Composition	✓	
830.1600	Description of materials used to produce the product	✓	
830.1650	Description of formulation process	✓	
830.1670	Discussion on the formation of impurities	✓	
830.1700	Preliminary analysis <i>NA</i>		✓
830.1750	Certified limits (158.345)	✓	
830.1800	Enforcement analytical method	✓	

Guideline No.	Group B: Product Chemistry Data Study Title	Data submitted	
		Yes	No
830.6302	Color	✓	
830.6303	Physical State	✓	
830.6304	Odor	✓	
830.6314	Oxidation/Reduction (Chemical incompatibility)	✓	
830.6315	Flammability	✓	
830.6316	Explosibility	✓	
830.6317	Storage stability	✓	
830.6319	Miscibility	✓	
830.6320	Corrosion Characteristics	✓	
830.6321	Dielectric Breakdown voltage	✓	
830.7000	pH	✓	
830.7100	Viscosity	✓	
830.7300	Density	✓	

R 300 and 301

New products must provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Cited	
		Yes	No
870.1100	Acute Oral (LD50)	✓	
870.1200	Acute Dermal (LD50)	✓	
870.1300	Acute Inhalation (LC50)	✓	
870.2400	Acute Eye Irritation	✓	
870.2500	Acute Dermal Irritation	✓	
870.2600	Dermal Sensitization	✓	

Efficacy – which guideline depends on the proposed label use and they must cite the data to be used for the bridging rationale.

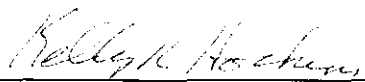
Guideline No.	Efficacy Study Titles	Cited		Comments
		Yes	No	
810.3100	Soil Treatments for Imported Fire Ants			
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments			
810.3300	Treatments to Control Pests of Humans and Pets	✓		
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments			
810.3500	Premises Treatments			
810.3600	Structural Treatments			
810.3800	Methods for Efficacy Testing of Termite Baits			



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX


Date: December 19, 2014		EPA Reg No./File Symbol: 2517-NEW		Page 1 of 4	
Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710		Product: Sergeant's® 9.1% Imidacloprid Spot On for Cats			
Ingredient: Imidacloprid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry					
830.1550, 830.1600, 830.1620, 830.1650, 830.1670, 830.1750	Group A Product Chemistry for Sergeant's 9.1% Imidacloprid Spot-on Products	49469201	Sergeant's Pet Care Products	OWN	
830.1800	Analytical Method for Sergeant's 9.1% Imidacloprid Spot-On Products	49469202	Sergeant's Pet Care Products	OWN	
830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6315, 830.6316, 830.6319, 830.6321, 830.7000, 830.7100, 830.7300, 830.7520	Summary of Group B Product Chemistry and Waivers for Sergeant's 9.1% Imidacloprid Spot-on Products	49469203	Sergeant's Pet Care Products	OWN	
830.6302, 830.7100, 830.7300	Physical and Chemical Characteristics: Color, Viscosity, and Density for Sergeant's 9.1% Imidacloprid Spot-on Products	49469204	Sergeant's Pet Care Products	OWN	
830.6317, 830.6320	Accelerated 14-Day Storage Stability and Corrosion Characteristics of Sergeant's 9.1% Imidacloprid Spot-on Products	49469205	Sergeant's Pet Care Products	OWN	
830.6315	Flashpoint for Sergeant's 9.1% Imidacloprid and 9.1% Imidacloprid + 0.46% Pyriproxyfen Spot-on Products	49469206	Sergeant's Pet Care Products	OWN	
Toxicology Data Requirements					
870.1100	Acute Oral Toxicity Study with Imidacloprid (Bay T-7391) 10% Pour On in Rats: Lab Project Number: 74585: 95-012-DO. Unpublished study prepared by Bayer Corp. 26 p.	43679601	Bayer HealthCare LLC	OLD	
870.1200	Acute Dermal Toxicity Study with Imidacloprid (Bay T-7391) 10% Pour On in Rats: Lab Project Number: 74584: 95-022-DQ. Unpublished study prepared by Bayer Corp. 24 p.	43679602	Bayer HealthCare LLC	OLD	
870.1300	Acute Four-Hour Inhalation Toxicity Study with Imidacloprid (Bay T-7391) 10% Pour On in Rats: Lab Project Number: 74589: 94-042-CT. Unpublished study prepared by Bayer Corp. 31	43679603	Bayer HealthCare LLC	OLD	
870.2400	Primary Eye Irritation Study with Imidacloprid (Bay T-7391) 10% Pour On in Rabbits: Lab Project Number: 74588: 94-335-CO. Unpublished study prepared by Bayer Corp. 19 p.	43679604	Bayer HealthCare LLC	OLD	
Signature 		Name and Title Kelly R. Hoskins, Director of Regulatory Affairs		Date December 19, 2014	



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DATA MATRIX

Date: December 19, 2014		EPA Reg No./File Symbol: 2517-NEW		Page 2 of 4	
Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710		Product: Sergeant's® 9.1% Imidacloprid Spot On for Cats			
Ingredient: Imidacloprid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2500	Primary Dermal Irritation Study with Imidacloprid (Bay T-7391) 10% Pour On in Rabbits: Lab Project Number: 74586: 94-325-CN. Unpublished study prepared by Bayer Corp. 19 p.	43679605	Bayer HealthCare LLC	OLD	
870.2600	Dermal Sensitization Study with Imidacloprid (Bay T-7391) 10% Pour On in Guinea Pigs: Lab Project Number: 74587: 94-324-CW. Unpublished study prepared by Bayer Corp. 24 p.	43679606	Bayer HealthCare LLC	OLD	
870.7200	Acute Toxicity Evaluation for Dermal Treatment of Cats with Imidacloprid (Bay t 7391) Spot-On: Lab Project Number: TR-94D-010: 74579. Unpublished study prepared by Miles Inc. Animal Health DeSoto Research Facility. 19 p	43679501	Bayer HealthCare LLC	OLD	
870.7200	General Safety Evaluation for Topical Use of Imidacloprid (Bay t 7391) Spot-On On Cats: Lab Project Number: TR-95F-006: 74591. Unpublished study prepared by Bayer Corp. DeSoto Research Facility. 41 p	43679502	Bayer HealthCare LLC	OLD	
870.7200	General Safety Evaluation for Topical Use of Imidacloprid (Advantage) Spot-On on Six Week Old Kittens: Lab Project Number: 74746: TR-96F-004: 10332. Unpublished study prepared by Bayer Corp., DeSoto Research Facility. 41 p. Relates to L0000102.	44157301	Bayer HealthCare LLC	OLD	
870.7200	General Safety Evaluation for Topical Use of Imidacloprid (Advantage) Spot-On on Kittens Eight Weeks of Age: Lab Project Number: 74747: TR-96F-006: 10332. Unpublished study prepared by Bayer Corp., DeSoto Research Facility. 45 p. Relates to L0000102.	44157302	Bayer HealthCare LLC	OLD	
870.7200	Acute Oral Toxicity Evaluation of Imidacloprid (Advantage) in Cats: Lab Project Number: TR-96F-011: 74769: J:\USERS\LINDA\NOREPORT\JAS0173.RP. Unpublished study prepared by Bayer Corp., Animal Health. 10 p.	44179802	Bayer HealthCare LLC	OLD	
Signature 		Name and Title Kelly R. Hoskins, Director of Regulatory Affairs		Date December 19, 2014	

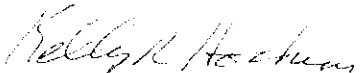


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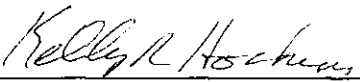
Date: December 19, 2014		EPA Reg No./File Symbol: 2517-NEW		Page 3 of 4	
Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710		Product: Sergeant's® 9.1% Imidacloprid Spot On for Cats			
Ingredient: Imidacloprid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Performance Test Guidelines					
810.3300	Efficacy Evaluation of Bay t 7391 (Imidacloprid) 10% Solution Applied Dermally for Control of Fleas on Cats: Lab Project Number: MIC 194: 74571. Unpublished study prepared by Agresearch Consultants, Inc. 32 p.	43679503	Bayer HealthCare LLC	OLD	
810.3300	Efficacy Evaluation of Bay t 7391 (Imadacloprid) 10% Solution Applied Dermally for Control of Fleas on Cats: Lab Project Number: PD-7391-95F-004: 74581. Unpublished study prepared by Professional Laboratory and Research Services, Inc. (PLRS). 46 p.	43679504	Bayer HealthCare LLC	OLD	
810.3300	Efficacy Evaluation of BAY t 7391 (Imidacloprid) 10% Solution Applied Dermally for Control of Adult Fleas and Flea Eggs on Cats: Lab Project Number: BH036/95: 74634: 95REPORT/AUSTRALI.DOC. Unpublished study prepared by Bayer Australia Ltd. 33 p.	43794101	Bayer HealthCare LLC	OLD	
810.3300	Controlled Field Trials on the Efficacy and Tolerance of a Spot-On Formulation of Imidacloprid (BAY NTN 33893) 10% for Control of the Cat Flea (C. felis) in Domestic Cats: Lab Project Number: HVS 95-01: 74635: 95REPORT/74635.DOC. Unpublished study prepared by Institute of Parasitology, Hannover Vet School. 7 p.	43794102	Bayer HealthCare LLC	OLD	
810.3300	Comparative Evaluation of How Quickly Advantage and Frontline (Fipronil) Top Spot Kill Fleas on Dogs: (final Report): Lab Project Number: 74800: PLRS 9665: 150.341. Unpublished study prepared by Professional Laboratory & Research Services, Inc. 51 p.	44256901	Bayer HealthCare LLC	OLD	
810.3300	Imidacloprid Topical Formulation: Larvicidal Effect Against Ctenocephalides felis in the Surroundings of Treated Dogs: (Revised Report): Lab Project Number: 74828: 97REPORT/ARTHER/HOPKINS.DOC. Unpublished study prepared by Bahrs Hill Research Station. 14 p.	44256902	Bayer HealthCare LLC	OLD	
Signature 		Name and Title Kelly R. Hoskins, Director of Regulatory Affairs		Date December 19, 2014	



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Ingredient: Imidacloprid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Performance Test Guidelines					
810.3300	Evaluation of the Effects of Shampooing or Water Immersion on the Initial and Residual Efficacy of Advantage for Flea Control on Dogs: Lab Project Number: BD#296: 150.353: BD 296.Unpublished study prepared by AgResearch Consultants, Inc. 27 p.	44256903	Bayer HealthCare LLC	OLD	
Signature 		Name and Title Kelly R. Hoskins, Director of Regulatory Affairs		Date December 19, 2014	

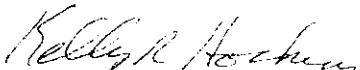


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Ingredient: Imidacloprid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Sergeant's Pet Care Products	OWN	
			Sergeant's Pet Care Products	OWN	
			Sergeant's Pet Care Products	OWN	
			Sergeant's Pet Care Products	OWN	
			Sergeant's Pet Care Products	OWN	
			Sergeant's Pet Care Products	OWN	
			Sergeant's Pet Care Products	OWN	
			Bayer HealthCare LLC	OLD	
			Bayer HealthCare LLC	OLD	
			Bayer HealthCare LLC	OLD	
			Bayer HealthCare LLC	OLD	
Signature 		Name and Title Kelly R. Hoskins, Director of Regulatory Affairs		Date December 19, 2014	



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Ingredient: Imidacloprid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer HealthCare LLC	OLD	
			Bayer HealthCare LLC	OLD	
			Bayer HealthCare LLC	OLD	
			Bayer HealthCare LLC	OLD	
			Bayer HealthCare LLC	OLD	
			Bayer HealthCare LLC	OLD	
			Bayer HealthCare LLC	OLD	
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Ingredient: Imidacloprid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note

Product Performance Test Guidelines

	Bayer HealthCare LLC	OLD	
	Bayer HealthCare LLC	OLD	
	Bayer HealthCare LLC	OLD	
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	Bayer HealthCare LLC	OLD	
	Bayer HealthCare LLC	OLD	

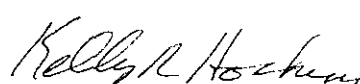
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Ingredient: Imidacloprid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer HealthCare LLC	OLD	
Signature 		Name and Title Kelly R. Hoskins, Director of Regulatory Affairs		Date December 19, 2014	

Sergeant's® Master Label

19 December 2014

Version 14.1

EPA Reg. No. 2517-NEW

Information in [] is optional.

Information in { } is note to reviewer.

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FRONT PANEL

**Cats Spot On
Imidacloprid**

[Optional text appears in brackets/parenthesis – the final label may include some or all of the optional text on front, back or side label panels]

Sergeant's® 9.1% Imidacloprid Spot On for Cats

[ABNs]

[SENTRY Vet for Cats Imidacloprid]
[SENTRY Vet Advanced Flea for Cats]
[SENTRY Vet FleaGuard for Cats]
[SENTRY Vet Vantage for Cats]
[SENTRY Vet Flea Vantage for Cats]
[SENTRY Advanced for Cats Imidacloprid]
[SENTRY Advanced FleaGuard for Cats]
[SENTRY Advanced Vantage for Cats]
[SENTRY Advanced Flea Vantage for Cats]
[SENTRY Advanced VetSpot for Cats]
[PetArmor Vantage for Cats]
[PetArmor Advant for Cats]
[PetArmor FleaGuard for Cats]
[PetArmor Advanced for Cats]
[PetArmor Flea Vantage for Cats]
[PetArmor Adv Flea for Cats]
[PetArmor Adv.Flea for Cats]
[PetArmor AdVet for Cats]

For use ONLY on cats [[&][and] kittens] [weighing] [2 [-][to] 9 lbs.] [[more than][over][>] 9 lbs.] and [over 8 weeks [old][of age]][8 weeks [of age] or older] {OR}
ONLY for cats [[&][and] kittens] [over 8 weeks [old][of age]][8 weeks [of age] or older] and [weighing] [2 [-][to] 9 lbs.] [[more than][over][>] 9 lbs.]

[Apply to [cats and] [kittens] over 8 weeks old]
[Apply to [cats and] [kittens] 8 weeks or older]

[Active Ingredient Reference Statements]

[Contains imidacloprid, [the] ~~[same]~~ active ingredient used in [Advantage® 9 Topical Solution] [Advantage® for Small Cats] [DefenseCare Flea Protection Small Cat] [Advantage® TM 9 (Imidacloprid) Topical Solution].*]
[Contains imidacloprid, [the] ~~[same]~~ active ingredient used in [Advantage® 18 Topical Solution] [Advantage® for Large Cats] [DefenseCare Flea Protection Large Cat] [DefenseCare Flea Protection Large Cats] [Advantage® 18 (Imidacloprid) Topical Solution].*]

[Compare to the active ingredient in [Advantage® 9 Topical Solution] [Advantage® for Small Cats] [DefenseCare Flea Protection Small Cat] [Advantage® TM 9 (Imidacloprid) Topical Solution].*]

[Compare to the active ingredient in [Advantage® 18 Topical Solution] [Advantage® for Large Cats] [DefenseCare Flea Protection Large Cat] [DefenseCare Flea Protection Large Cats] [Advantage® 18 (Imidacloprid) Topical Solution].*]

e-Submission

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[Contains [the] ~~[same]~~ active ingredient used in in [Advantage[®] 9 Topical Solution] [Advantage[®] for Small Cats] [DefenseCare Flea Protection Small Cat] [Advantage[®] TM 9 (Imidacloprid) Topical Solution].*]

[Contains [the] ~~[same]~~ active ingredient used in in [Advantage[®] 18 Topical Solution] [Advantage[®] for Large Cats] [DefenseCare Flea Protection Large Cat] [DefenseCare Flea Protection Large Cats] [Advantage[®] 18 (Imidacloprid) Topical Solution].*]

[Compare to [Advantage[®] 9 Topical Solution] [Advantage[®] for Small Cats] [DefenseCare Flea Protection Small Cat] [Advantage[®] TM 9 (Imidacloprid) Topical Solution], contains the same active ingredient.*]

[Compare to [Advantage[®] 18 Topical Solution] [Advantage[®] for Large Cats] [DefenseCare Flea Protection Large Cat] [DefenseCare Flea Protection Large Cats] [Advantage[®] 18 (Imidacloprid) Topical Solution], contains the same active ingredient.*]

At
[[Brand Name] [products] [This product] contain(s) imidacloprid, [the] [same] [an] active ingredient used in in [Advantage[®] 9 Topical Solution] [Advantage[®] for Small Cats] [DefenseCare Flea Protection Small Cat] [Advantage[®] TM 9 (Imidacloprid) Topical Solution].*]
[[Brand Name] [products] [This product] contain(s) imidacloprid, [the] [same] [an] active ingredient used in in [Advantage[®] 18 Topical Solution] [Advantage[®] for Large Cats] [DefenseCare Flea Protection Large Cat] [DefenseCare Flea Protection Large Cats] [Advantage[®] 18 (Imidacloprid) Topical Solution].*]

[[Brand Name] [products] [This product] contain(s) imidacloprid, compared to [the] [same] active ingredient used in in [Advantage[®] 9 Topical Solution] [Advantage[®] for Small Cats] [DefenseCare Flea Protection Small Cat] [Advantage[®] TM 9 (Imidacloprid) Topical Solution].*]
[[Brand Name] [products] [This product] contain(s) imidacloprid, compared to [the] [same] active ingredient used in in [Advantage[®] 18 Topical Solution] [Advantage[®] for Large Cats] [DefenseCare Flea Protection Large Cat] [DefenseCare Flea Protection Large Cats] [Advantage[®] 18 (Imidacloprid) Topical Solution].*]

[[*][Brand Name][This product] is not manufactured or distributed by [Bayer Healthcare LLC] [Company name], the makers of [Advantage[®] 9 Topical Solution] [Advantage[®] for Small Cats] [DefenseCare Flea Protection Small Cat] [Advantage[®] TM 9 (Imidacloprid) Topical Solution].]
[[*][Brand Name][This product] is not manufactured or distributed by [Bayer Healthcare LLC] [Company name], the makers of [Advantage[®] 9 Topical Solution] [Advantage[®] for Small Cats] [DefenseCare Flea Protection Small Cat] [Advantage[®] TM 9 (Imidacloprid) Topical Solution].]

[*[Advantage[®] 9 Topical Solution] [Advantage[®] for Small Cats] [DefenseCare Flea Protection Small Cat] [Advantage[®] TM 9 (Imidacloprid) Topical Solution] is a registered trademark of Bayer Healthcare LLC.]

[*[Advantage[®] 18 Topical Solution] [Advantage[®] for Large Cats] [DefenseCare Flea Protection Large Cat] [DefenseCare Flea Protection Large Cats] [Advantage[®] 18 (Imidacloprid) Topical Solution] is a registered trademark of Bayer Healthcare LLC.]

[Fleas]

[Prevents [further] flea infestation for [[four][4] weeks][1 month] with [just] one [treatment][application]

[Brand Name] Prevents flea infestation for [four][4] weeks][1 month]

[Kills fleas within 12 hours [of application] on cats]

Sergeant's[®] Master Label

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[Kills reinfesting fleas within 2 hours]

[Kills [adult] fleas before they lay eggs]

[[Brand Name]][This product] kills fleas and may reduce the incidence of a hypersensitivity skin disorder called flea allergy dermatitis (FAD), which may be caused by the feeding activity of fleas on cats.]

[Kills flea larvae in cat's environment following contact with treated cat]

[Apply monthly [for optimal flea control] [to control and prevent fleas]]

[Kills fleas]

[Complete Flea [Control] [Protection]]

[Optimal Flea [Control] [Protection]]

[Advanced Flea [Control] [Protection]]

[Kill fleas in 12 hours, continues to kill for 4 weeks]

[Kills fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation]

[Kills fleas, which may be a source of flea allergy dermatitis [, within][in] 12 hours]

[Stops and prevents infestation of listed pests for 4 weeks]

[Use of [Brand Name][this product]] kills fleas and may reduce incidence of [flea bite hypersensitivity] [and][or] [flea allergy dermatitis] [FAD]]

[Monthly treatment with [Brand Name][this product] kills fleas and may reduce incidence of [flea bite hypersensitivity] [and][or] [flea allergy dermatitis] [FAD]]

[Flea protection]

[Active against fleas]

[Kills fleas on [kittens] [and] [cats]]

[[Brand Name] Offers protection against fleas]

[Flea control for cats and kittens [over 8 weeks [old]][of age]][8 weeks [of age] or older]]

[Kills fleas within 12 hours [and prevents flea infestations for [a][one] [month] [four weeks]]]

[All Others]

[[Sergeant's] Caring For Your Pets Since 1868]

[For Cats]

[Specially Formulated for Cats and Kittens [Over 8 Weeks [Old]][of Age]][8 Weeks [of Age] or Older]]

[Specially Formulated for Cats and Kittens (8 weeks or older)]

[Cats and Kittens [over 8 weeks [old]][of age]][8 weeks [of age] or older]]

[Can be used on kittens [over 8 weeks [old]][of age]][8 weeks [of age] or older]]

[The Only Flea Protection You Need For Your Cat[s]!]

[Original Vet Strength]

[Fast Acting] [Long Lasting]

[Convenient]

[Easy application]

[Easy to apply product]

[Easy to Use [Application]]

[One Step Hassle Free Protection!]

[Waterproof]

[Remains effective, even after bathing, water immersion, or exposure to [sunlight] [and][or] [rain]]

[Once a month treatment]

[Apply once every [4 weeks] [month] [30 days]!]

[4 Week Dose!] [1 Month Dose!] [30 Day Dose!]

[For year-round protection, apply [Brand Name][this product] monthly]

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[Best if used year round!]

[X Applications]	[4 Week Supply]	[1 Month Supply]
[One Application]	[8 Week Supply]	[2 Month Supply]
[Two Applications]	[12 Week Supply]	[3 Month Supply]
[Three Applications]	[16 Week Supply]	[4 Month Supply]
[Four Applications]	[20 Week Supply]	[5 Month Supply]
[Five Applications]	[24 Week Supply]	[6 Month Supply]
[Six Applications]	[48 Week Supply]	[12 Month Supply]
[9 Applications]	[52 Week Supply]	[24 Month Supply]
[12 Applications]	[104 Week Supply]	
[24 Applications]		

[[for] Small Cat[s] [2 to 9 lbs.]]

[[for] Large Cat[s] [Over 9 lbs.]]

[Direct to skin [tube][vial][applicator][pipette]]

[Easy to Use] [tube][vial][applicator][pipette]

[Clean cut [open] [tube][vial][applicator][pipette]]

[No-mess [open] [tube][vial][applicator][pipette]]

[Clip-tip design [tube][vial][applicator][pipette][!]]

ACTIVE INGREDIENT:

Imidacloprid.....9.10%

OTHER INGREDIENTS:90.90%

[TOTAL 100.00%]

KEEP OUT OF REACH OF CHILDREN WARNING

[See [Back][or][Side][Label[s]][Panel[s]] for Additional Precautionary Statements]

NET CONTENT: X fl oz [Y – X fl oz applicators]

[0.014 fl oz (0.4 mL) [tubes][vials][applicators][pipettes]]

[0.027 fl oz (0.8 mL) [tubes][vials][applicators][pipettes]]

{END – FRONT PANEL}

BACK PANEL/SIDE PANEL OR INSERT

**Cats Spot-On
Imidacloprid**

[The active ingredient in [Brand Name][this product] is [imidacloprid,] formulated for fast acting [and long lasting] control of fleas on cats.] [[Brand Name][This product] kills fleas within 12 hours and prevents further flea infestations for [up to] [[4][four]weeks][1][one] month][30 days].]

Sergeant's® Master Label

19 December 2014

Version 14.1

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Information in [] is optional.

Information in { } is note to reviewer.

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READ ENTIRE LABEL BEFORE EACH USE.
USE ONLY ON CATS AND KITTENS 8 WEEKS OF AGE OR OLDER.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. WARNING. Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Harmful if swallowed. Avoid contact with skin. Wash hands thoroughly with soap and warm water after handling.

HAZARDS TO DOMESTIC ANIMALS. For external use on cats only. Individual sensitivities, while rare, may occur after using ANY pesticide product for cats. Do not treat your cat with more than one pesticide product at a time. Over dosing your cat can result in serious illness and even death. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing cats.

FIRST AID	
If In Eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If Swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If on Skin or Clothing	<ul style="list-style-type: none">• Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-781-4738 for emergency medical treatment information.	
NOTE TO PHYSICIAN	
Treat the patient symptomatically.	

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR CAT, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. Do not use on animals other than cats. Do not allow your cat to ingest this product. Do not use on kittens under 8 weeks of age. Do not apply to cats weighing less than [2][9] lbs. Use entire contents of [tube][vial][applicator][pipette] on each cat. [Do not split one [tube][vial][applicator][pipette] between two cats.] Do not use multiple [tube][vial][applicator][pipette]s on one cat. Weigh your cat to be sure you are applying the right dose formulated for the weight of your cat. Separate the treated cat from all other cats and dogs for 24 hours after treatment has been applied.

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Side Effects: Monitor your cat after application. [Some cats may experience temporary startle effects when any product is applied.] Cats may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe your cat with a mild soap and rinse with large amounts of water. If these or other side effects occur, consult your veterinarian or call 1-800-781-4738. If your cat has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your cat and continue to monitor your cat for the next 24 hours.

{OUTER PACKAGING}

How to open: Remove product [tube[s]][vial[s]][applicator[s]][pipette[s]] from the package. [Separate one [tube][vial][applicator][pipette] from the others.] Hold the [tube][vial][applicator][pipette] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply: While holding the cat with one hand, use the other hand to apply the solution. Invert the [tube][vial][applicator][pipette] and use the narrow end to part the cat's hair. Apply contents of one [tube][vial][applicator][pipette] of [Brand Name] [this product] to the cat's skin, as directed below. When finished, wrap the [tube][vial][applicator][pipette] in paper and put into the trash. Only one [tube][vial][applicator][pipette] per treatment is needed.

{For cartons containing 0.4 mL (0.014 fl oz) applicator tubes}

Only For Cats Weighing 2-[to] 9 lbs. [Do not apply to cats weighing less than 2 lbs.]

[including small cats or kittens, only 8 weeks or older] Apply one

[tube][vial][applicator][pipette] 0.4 mL (0.014 fl oz [directly to skin] as a spot between the shoulder blades. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat.

{For cartons containing 0.8 mL (0.027 fl oz) applicator tube}

Only For Cats Weighing Over 9 lbs. [Do not apply to cats weighing less than 9 lbs.] Apply one [tube][vial][applicator][pipette] 0.8 mL (0.027 fl oz) [directly to skin] as a spot between the shoulder blades. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat.

FREQUENCY OF APPLICATION

[Use [Brand Name][this product] monthly for control of flea[s] [infestations].] [[Studies show that] [Brand Name][This product] kills fleas within 12 hours of application and [lasts][protects] [for [up to] [[four][4] weeks][30 days][one month].] [[Brand Name][This product] kills reinfesting fleas within [2][two] hours and prevents further infestations of fleas [for [up to] [[four][4] weeks][30 days][one month]].] [If your cat is at high risk for flea reinfestation [,or in a highly infested environment], apply monthly.] [Apply monthly for optimal flea control.] [[Brand Name][This product] is waterproof and remains effective, even after water immersion or exposure to sunlight [and][or] [rain].] [Allow treated area to dry thoroughly.] [Do not reapply for [4 weeks][30 days].]

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STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove [tube][vial][applicator][pipette] from pack until ready to use. Store in a cool (below 77°F/[/][25°C]), dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

CONTAINER DISPOSAL: **If empty:** Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[WARRANTY

Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. The directions for use of this product are believed to adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer. Sergeant's is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Sergeant's, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: [Sergeant's][SENTRY] Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

[Satisfaction Guaranteed][If you are not satisfied, we will make it right with a replacement or refund.]

In Case of Emergency, call: 1-800-781-4738
Non-Emergency, call: 1-800-224-PETS (7387)

[Coupon(s) inside or on outside of box]
[Made in USA]

[Distributed by:] [Manufactured by:]
Sergeant's Pet Care Products, Inc.
Omaha, NE 68138-3710

EPA Reg. No. 2517-NEW
EPA Est. No. XXXXX-XX-XX
[BAR CODE AREA]

{END - BACK/SIDE PANEL}

{START - OPTIONAL PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT PACKAGE}

[How to Apply – May contain graphics illustrating product use, e.g., cat with a drop falling onto its neck from a tube/vial on front, side, or back carton label and/or applicator labeling.]

[Clip. Part. Squeeze.]

Easier-than-ever applicator lets you *clip* the tip, *part* the fur and *apply* directly to the skin – putting proven flea protection where it needs to be.]

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[Application Instructions][Directions for Use]

How to Open:

1. Remove product [tube[s]][vial[s]][applicator[s]][pipette[s]] from the package.
2. [Separate one [tube][vial][applicator][pipette] from the others.] Hold the [tube][vial][applicator][pipette] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply:

1. Invert [tube][vial][applicator][pipette] over cat and use open end to part cat's hair.
2. Apply contents of one [tube][vial][applicator][pipette] [of] [Brand Name] as a spot between the shoulder blades. Squeeze tube firmly to apply all of the solution to the cat's skin.

[Look at the Label (Look at the Label icon) [Easy] 6 Step [Easy] [Spot On] [Squeeze-On] [Topical] Checklist]

- [1] Read the label completely and follow directions
- [2] Weigh your cat
- [3] Do NOT use dog products on cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals after [treatment] [application] to avoid chance of ingestion
- [6] Do NOT split [tube][vial][applicator][pipette] between cats][and use the ENTIRE [tube][vial][applicator][pipette] contents]

[Brand Name][This product]

[Monthly reminder card]

[1][2][3][4][5][6][12][24][Month [Treatment] [Application] Tracker][Carecard]

[For year round protection apply [Brand Name][this product] monthly.]

[Cat's Name (Empty blank for owner to fill in name)]

[Cat's Weight (Empty blank for owner to fill in name)]

[First][1st] [Second][2nd] [Third][3rd] [Fourth][4th] [Fifth][5th] [Sixth][6th] [Seventh][7th]

[Eighth][8th] [Ninth][9th] [Tenth][10th] [Eleventh][11th] [Twelfth][12th]

[Dose] [Treatment] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)

[Application Date] [Date of Application]

[Calendar stickers with [Brand Name]

[Place stickers on your calendar as a reminder to reapply [Brand Name][this product] in 30 days.]

[Monthly Application Reminder Magnet (image of reminder magnet)]

[Place sticker on your calendar [or refrigerator] to remind yourself to apply [Brand Name][this product] to your cat]

[33% More Free]

[Bonus Size]

[Buy 3 get 1 free]

[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days, the reminder light will blink, reminding you to reapply [Brand Name][this product]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

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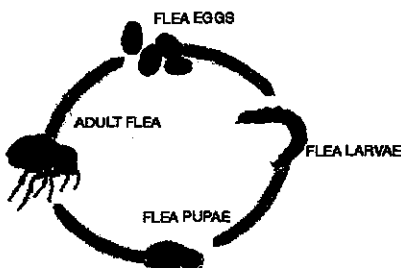
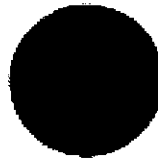
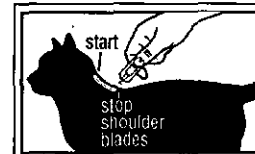
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[Each optional graphic below may or may not appear anywhere on the finished label]

	Adult Flea	
	Fleas	
	Flea Larvae	



MADE IN THE
USA

MADE IN THE
USA
WITH GLOBAL MATERIALS

[Flea life cycle diagram] [Flea Life Cycle]

{END – OPTIONAL INSERT OR PACKAGE COPY}

TUBE/VIAL LABEL

Cats Spot On
Imidacloprid

{Front Label}

{Back Label}

[Brand Name (for Cats)]

[X-Y] lbs. ≥8 wks

Imidacloprid 9.10%

0.014 fl oz (or) 0.027 fl oz {label code}

{EPA REG No may be on either the front or back label}

KEEP OUT OF REACH OF CHILDREN

WARNING: Read directions and precautions before using. Use scissors to open.

EPA REG. No. 2517-XXX

{label code}

{END – TUBE/VIAL LABEL}

